

Local Knowledge and the Social Dimensions of Risk

The Case of Animal Biopharming in New Zealand.

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Abstract:

This thesis analyses the social dimensions of the risk of animal biopharming (the genetic modification of animals to produce pharmaceuticals) in New Zealand, in the context of a wider discussion of the social nature of risk. In doing so, it offers a different conception of risk and risk assessment than is currently used within the government policy of New Zealand. Current policy has focused on technical evaluations of risk, in which the technology being analysed is not assessed within the social context it will enter and risk is compartmentalised into quantifiable and standardised data. This approach both serves to legitimate ‘experts’ as the true judge of risk, and also isolates members of the wider public to the realm of ‘ethical’ discussion and participation. Such policy, I argue, does not lend itself to good decision-making, as risk management procedures, built on the back of risk assessment, often prove to be impractical when entering complex and ambiguous social environments. Likewise, this form of risk assessment often fails to account for risk that could be identified by those with in-depth knowledge of the environment, both social and physical, that the technology will enter.

This thesis pilots aspects of an alternative approach, which aims to elicit information about the relevant environment. It demonstrates how one might identify and interview those with what is termed here as ‘local knowledge’, and how that knowledge can make a significant contribution to risk identification and assessment and the identification of social implications. The thesis concludes not only that local knowledge can contribute practically to risk assessment, but also that the concepts of risk and expertise must be widened to include social and contextual behaviour and knowledge.

A note on terminology:

The terms ‘transgenic animal’ and ‘GM animal’ are used interchangeably throughout this thesis; both refer to a genetically modified animal. The term ‘biopharm animal’ refers specifically to animals that have been genetically modified to produce pharmaceutical substances.

List of Acronyms:

BSE	Bovine Spongiform Encephalopathy
DDT	dichloro-diphenyl-trichloroethane
ERMA	Environmental Risk Management Authority
FDA	Food and Drug Administration (US)
FMD	Foot and Mouth Disease
GM	Genetically Modified
GMO	Genetically Modified Organism
GRAS	Generally Recognised as Safe
HSNO	Hazardous Substance and New Organisms Act
ISBCs	Institutional Biological Safety Committees
MAF	Ministry of Agriculture and Forestry
MFE	Ministry for the Environment
MoRST	Ministry of Research and Science Technology
MoH	Ministry of Health
NZTE	New Zealand Trade and Enterprise
RMA	Resource Management Act

Chapter 1: Introduction

Animal biopharming, the genetic engineering of animals in order to produce pharmaceuticals or other medically useful substances, has been touted as a potential area of economic growth and advantage within New Zealand. The predicted benefits of the technology are many; including cheaper medicine, greater access to transplantable organs and foreign economic investment to name a few (Beckman & Goldberg 2003; MoRST 2005). A report prepared by the Ministry of Research, Science and Technology (MoRST) in 2005 predicts that animal biopharming will be active within New Zealand by 2008, to the point that ‘factories’ of livestock will develop across the country. Already several field tests aimed at developing commercially viable animal biopharming applications have been conducted in ‘contained’ environments within New Zealand, with varying levels of success. If these predictions and expectations hold true, what will the social implications of this technology be for New Zealand?

This thesis will explicate the social dimensions of animal biopharming. This will be achieved primarily by identifying and exploring sources of relevant ‘local knowledge’ that are not typically incorporated into official risk assessment processes. ‘Local knowledge’ refers to the knowledge individuals or communities hold through their personal experiences in areas that will be affected by, or affect, animal biopharming. ‘Social implications’ has two meanings within this thesis. Firstly, this can mean the implications of social practices for the safety of animal biopharming operations. Secondly, it can be defined as the implications of animal biopharming for common social practices that interact with the technology.

Theoretical Framework

Both national and international discussion has begun on the possible implications of animal biopharming. While much of this discussion has been optimistic (Powell 2001; Beckman & Goldberg 2003), some writing points to areas of potential concern (U.S National Research Council Committee on Biological Confinement of Genetically Engineered Organisms 2004). Along with this discussion, several applications to conduct field tests of animal biopharming have gone through the risk assessment

procedure within New Zealand, which suggests that it is recognised that animal biopharming may potentially pose some risks for New Zealand.

However, risk assessment is not complete without an understanding of how the technology is likely to interact with the social practices it will encounter if implemented. Risk assessment has tended to focus either on laboratory and technical examination of risks, or a normative discussion of risks with the public. Although both of these processes are undoubtedly important, this thesis seeks to evaluate the risks of the technology in relation to its everyday use outside of an isolated experimental environment and beyond normative claims from the public. In order to do this, those who would be implicated in the implementation of the technology must be allowed to contribute their experiential knowledge and analysis of how the technology would play out in their context. The knowledge gained will complement risk assessment processes by providing additional assessment information on the practicalities and implications of probable regulations.

This thesis is grounded on literature in the areas of local knowledge and public participation in decision-making on issues involving science and technology. Some of this literature suggests that knowledge about the implications of the technology is spread across society outside of traditional technical and policy-making realms. This knowledge, which is often based on experience within a local environment relevant to a new technology, can contribute to risk assessment. Firstly, local knowledge can contribute generally to the understanding of risks involved with a technology and its use, both technical and social, and to the formation of regulatory guidelines regarding its use. Secondly, local knowledge can specifically help us understand how the technologies and its regulations will impact upon members of society, culturally, economically and socially.

Rationale

This approach can add to the policy discussion on biopharming in New Zealand, as well as to our understanding of local knowledge and of risk. Current discussions over biotechnology in general and biopharming in particular, generally frame the issues as belonging to two different domains, those of the experts, and the public at large. This approach, although not explicitly, implies that society and the science sector can be

separated into compartments of opinion and knowledge. Technology experts, such as bio scientists, predict tremendous progress for both humanitarian health initiatives and economic fields, where biopharming can produce drugs cheaply and efficiently (Kues & Niemann 2004, p.287), whilst also holding the potential to treat as yet incurable diseases such as multiple sclerosis¹. The knowledge of technical experts is often represented as constituted by ‘objective’ facts, with normative issues left out of the equation. On the other side of the discussion, NGO’s and members of the general public are represented as holding normative concerns about biopharming, and these normative concerns are elicited through ‘dialogues’ and consultations, such as those carried out by the Bioethics Council (The Bioethics Council (c)) regarding xenotransplantation. However the practical concerns that the public and NGO’s may hold do not have a regular avenue for expression. Thus, framing of the debate has created two different arenas with their own associated actors, the objective discussion of biopharming from experts and the normative concerns from the public.

However, this division of public opinion and expert knowledge limits the risk assessment of biopharming’s implementation in New Zealand. By separating the two fields, public and science, an exchange of knowledge tends to be one way, usually from the ‘experts’ to the public, while occasionally the science sector is encouraged to take public values into account. The separation also ignores the social complexity within which opinions and knowledge of biopharming is formed. Representation of technical expertise versus public values suggests that technological facts and opinions are created within a vacuum outside of societal influence. Risk assessment is left to the experts, who often assume that risk itself is discovered within a realm that is testable, quantifiable and value-free.

As a result of this approach, recommendations to manage risks often work upon the assumption of what is possible in an isolated environment. When exposed to the real social worlds they will enter, which includes unpredictable environments and unregimented behaviour, these recommendations can be revealed as impractical and, at times, plainly irrational. In practice, people may be likely to adopt ways of doings

¹ New Zealand CRI, AgResearch, is developing cows that will produce proteins to potentially treat multiple sclerosis (Ministry for the Environment (b)).

things that are familiar, or may seem to them to be easier and more efficient, but which deviate from what is prescribed or assumed to be controlled for.

In this way, certain individuals and communities outside the policy-making sector may hold more knowledge of the way a technology will be used away from an isolated experimental environment than ‘experts’ do (Irwin & Michael 2003). The theory is concerned not with what the rules are regarding technical procedure, but what are the actual practices that will be involved in this procedure. This point assumes that members outside the scientific community hold knowledge that cannot be obtained through isolated scientific experiment, particularly regarding social practices and interaction with a new technology. If this is the case, it is both possible and necessary to search for, and extrapolate, sources of this knowledge in order to better understand how a technology will affect certain localities socially and how, in turn, its risk should be viewed.

Background information and definitions

Animal biopharming is a technically complex topic. Several procedures can be used to biopharm animals (Dyck et al. 2003), however as of yet there has been no commercial approval of an animal biopharmed product (U.S. National Research Council Committee on Defining Science-based Concerns Associated with Products of Animal Biotechnology 2002, p.51; Pollack 2006). Thus, its development remains in the pre-commercial stages. This next section will not attempt a technically detailed explanation of animal biopharming processes and issues². However, a general description and definition of animal biopharming is necessary for the sake of clarity.

One of the more recent developments within biotechnology is the genetic modification of animals. Genetic modification refers to the process of manipulating genes as well as transferring them into other organisms (Mehta & Gair 2001, p.242). The process of biopharming is defined as genetically modifying crop plants or animals in order to produce pharmaceutical or medically useful substances. Biopharm animals can therefore be defined as, “transgenic animals modified to produce proteins

² More detailed discussions of animal biopharming processes can be found at (Dyck 2003) and (U.S National Research Council Committee on Defining Science-based Concerns Associated with Products of Animal Biotechnology 2002).

for extraction, purification, therapeutic use” (U.S. National Research Council Committee on Defining Science-based Concerns Associated with Products of Animal Biotechnology 2002, p.149)³. A transgene is “a gene introduced into an organism by human intervention” (U.S. National Research Council Committee on Defining Science-based Concerns Associated with Products of Animal Biotechnology 2002, p.157). This has the potential to produce large amounts of expensive products at a relatively inexpensive rate.

There are several proposed advantages of animal biopharming as documented in the literature. Perhaps the most attractive feature of animal biopharming is the potential to produce “large amounts of valuable products at relatively low expense as compared to” traditional laboratory-based production methods of pharmaceuticals (U.S. National Research Council Committee on Defining Science-based Concerns Associated with Products of Animal Biotechnology 2002). Cost savings are seen as resulting in part from enabling greater flexibility of scale- rather than building laboratories, one need only increase the size of the herd.

The diversification of dairy production away from a high-volume commodity production system, toward higher value products, is considered important to the future economic well-being of the dairy industry specifically and New Zealand more generally. Animal biopharming is seen as one way to reach this goal (New Zealand Association of Crown Research Institutes. 2000).

New Zealand is promoted as a particularly attractive destination for biopharming companies because of its strong farming sector, its relative isolation from animal disease (particularly from Bovine Spongiform Encephalopathy (BSE)), and its focus on the ‘knowledge economy’ which is conducive to the research and development required for animal biopharming. Some of the proposed products of biopharming to be produced within New Zealand are vaccines, human serum proteins, designer milk and nutraceuticals and organ transplants (Beckman & Goldberg 2003, p. 11).

³ There are other uses of GM that parallel biopharming procedures, but produce different substances. For instance, research is being conducted to produce industrial plastics through biopharming techniques. However, as little research has been conducted into this type of production within New Zealand, this thesis will focus on medical applications.

There are several risks of animal biopharming already reported in the literature. The chance of biopharmed products or animals entering the food chain could have human health risks and economic repercussions for both non GM farmers and GM farmers alike. Examples of GM corn entering the food chain, such as the Starlink corn (Schmitz, Schmitz & Moss 2005), have illustrated the level of this impact and are discussed in chapter five. It will be necessary to avoid non-GM cows mixing with GM cows in order to prevent inadvertent mixing and possibly other forms of inadvertent transgene flow. The risk of horizontal gene transfer⁴ is also potentially an issue, with the opportunity for GM material being transferred to non GM organisms through animal waste or blood in the soil, or through insects, a possibility. Another risk is the “generation of potentially pathogenic viruses by recombination between sequences of the vector used to introduce a transgene and related, but non-pathogenic, viruses that might be present in the same animal” (U.S. National Research Council Committee on Defining Science-based Concerns Associated with Products of Animal Biotechnology 2002, p.52). Obviously such an occurrence could have severe human health and environmental repercussions for the future.

It is likely that controls will be put in place to minimise these risks if animal biopharming enters commercial production. For example, current field tests require certain controls such as two metre high fencing with buffer zones between the areas of fencing, as well as disposal controls and isolation (Ministry of Agriculture and Forestry 1999). If these controls are extended to commercial operations, this will in turn affect the social practices of those producing animal biopharming. However, the practicalities of these controls will also be affected by the social practices of those engaging in animal biopharming. This thesis suggests it is necessary to use the local knowledge of those within the social environment animal biopharming will enter to understand its true implications and risks.

Method

The methodology of this thesis is based largely upon a working paper by Joanna Goven, Fiona Cram and Jane Gilbert which builds upon the theories of Wynne, Irwin and others regarding social knowledge (Goven, Cram & Gilbert 2004, p.2). The paper

⁴ The transfer of GM material apart from mother or father to offspring.

develops a method to identify and collect local knowledge that is useful for identifying future risks and implications of new technologies. One of the challenges of this method is to identify individuals who may hold relevant local knowledge. As this type of knowledge has rarely been elicited formally, it may be the case that those who hold relevant knowledge are unaware that they have something to offer. Thus, it is important to actively identify areas which may be relevant to social implications, rather than passively wait for those with relevant knowledge to present themselves.

The first stage of this method follows the traditional practice of finding and analysing related research in the area of biopharming. This process will be referred to as 'scoping' throughout the thesis. Through scoping relevant sources, it was possible to locate some of the relevant areas of local and social practice which relate to animal biopharming. Government reports, NGO websites, public dialogues and academic literature are useful forms of literature on both possible areas of local knowledge and an understanding of the regulatory landscape regarding animal biopharming in New Zealand. As animal biopharming in New Zealand is at a developmental and early stage, much of the literature identified was not specific to New Zealand's situation. Further scoping interviews with relevant policy makers, risk assessors and technology developers within New Zealand were necessary to identify possible avenues of development for animal biopharming. Five such individuals, from AgResearch, the Ministry of Science and Technology (MoRST), New Zealand Trade and Enterprise (NZTE) and the Environmental Risk Management Authority (ERMA), were identified and interviewed. After analysing the literature and interviews, it was possible to identify individuals or groups who may hold detailed knowledge of these social practices.

Dairy farmers were identified as individuals who may hold particularly relevant knowledge on how their practices may affect and be affected by animal biopharming in the future. Seven dairy farmers were interviewed, with experience in farming from Waikato, Taranaki and Canterbury. It was important to let the interviewee locate knowledge that may be useful. The semi-structured interview technique was employed by the researcher for this purpose. The interview schedule contained general questions and themes, derived from the previous scoping activities; however, the structure of the interview was dictated by the interviewee's responses. As the interviewee may have

had little exposure to the issues surrounding animal biopharming itself, background information was provided. It was also indicated to the interviewee why they may hold useful knowledge on the implications of animal biopharming.

Structure

The structure of the remainder of the thesis is described below.

Chapter Two discusses and analyses literature regarding the key assumptions and concepts of this thesis. First I examine the general themes throughout the literature on (what is referred to here as) local knowledge. Particular focus will be placed on the relation between local knowledge and public participation in practical decision making over complex technologies and risk assessment. In this light, social critiques of ‘technical’ risk assessment and the move toward normative participation will be reviewed. The chapter also frames how this thesis approaches local knowledge and risk assessment in the context of current literature.

Chapter Three discusses in more detail the method employed here. Particular focus is placed on how the thesis has actively identified, or ‘scoped’, relevant local knowledge in relation to a risk assessment of animal biopharming in New Zealand. A discussion of the semi-structured interviews follows; particularly in relation to how the method elicits relevant information on risks from those identified as holding local knowledge.

Chapter Four offers a discussion of current regulation and risk assessment within New Zealand. Firstly, a brief outline of the regulatory and risk assessment framework within New Zealand is given. The ability of this framework to incorporate local knowledge and to account for social implications of animal biopharming is analysed.

In Chapter Five the drivers and motivations pushing the development of biopharming within New Zealand are discussed, particularly in terms of how they affect future applications of animal biopharming. The processes of animal biopharming production will also be discussed and explored, as well as a discussion of the known risks of animal biopharming and the likely controls that will be placed on its commercial use. This discussion will highlight the social practices animal biopharming may affect or be affected by, and hence, suggest relevant holders of local knowledge in these areas.

Chapter Six explores the findings of interviews with dairy farmers, identified as holders of relevant local knowledge, and relates these to the risks and social implications of animal biopharming in New Zealand. More generally the approach of risk assessment in New Zealand will be discussed in light of the general themes of the interview findings.

Chapter Seven concludes the thesis with a discussion of the findings in relation to the risks and implications of animal biopharming in New Zealand, and the approach to risk assessment in New Zealand generally. Limitations of this thesis are discussed, and opportunities for further research are identified.

Conclusion

Finally, it should be noted that the purpose of this thesis is not to conduct a complete and accurate risk assessment of animal biopharming, but to pilot a new method for such a process. Thus, the number of interviews is too small to be considered adequate for risk assessment; however the interviews produced enough to show the value of this type of risk assessment, and gave results worthy of further investigation in themselves.

Chapter 2: Review of Relevant Literature

There is no single, unified definition of ‘local knowledge’. The fact that the term local knowledge shares many of the characteristics of, and is often used interchangeably with other terms such as ‘traditional knowledge’ (Berkes, Colding & Folke 2000), ‘indigenous knowledge’, ‘experiential knowledge’ (Caron-Flinterman, Broerse & Bunders 2005) and ‘situated knowledge’ (Lave 1993; Nygren 1999) should adequately indicate its vague nature within the literature (Antweiler 2004; Agrawal 1995)⁵. However, despite the lack of a unified definition, general themes throughout the literature point towards a working concept of local knowledge. Although the other terms utilised in the literature in many ways share these themes, the term local knowledge has been chosen for the current thesis as it is considered broad enough to include many of the more specific qualities shared by these terms.

The study of local knowledge has most often occurred within the context of the study of public understanding of science, decisions over complex technologies, hazardous materials and risk assessment, as well as the importance of public participation in sustainable development. It has also been used in discussions of participation in environmental management involving biodiversity, and can be identified in the literature of popular epidemiology. The issue of public participation is linked to the study of local knowledge because the involvement of the public in decision-making is contingent upon understandings of what knowledge is relevant to a decision. Participation is granted based on what knowledge is perceived as ‘legitimate’ knowledge, and who holds this knowledge (Irwin 1995, p.81). The question arises, what knowledge do lay members of the public hold, if any, relevant to decisions over science and technology? (Fischer 2000, p.10; Caron-Flinterman, Broerse & Bunders 2005). The study of what knowledge is held by individuals and communities outside the sphere of formal expertise and policy decision making is an avenue to understanding how the public can participate, and perhaps why they have often been excluded. Discussion of local knowledge is in this way connected to discussion of public participation in complex decision making (Irwin 1995).

⁵ Other terms used for local knowledge include civic, citizen, lay, and public knowledges, civic expertise, lay expertise, everyday knowledge, and community knowledge (Antweiler 2004).

This chapter will review the literature on local knowledge in relation to risk assessment and public participation in decisions about technology. It will firstly offer a description of the general themes that define local knowledge. A discussion of the public understanding of science and the deficit model in relation to the development of local knowledge will then be provided. Following this, an analysis of popular epidemiology will be offered, concluding with a discussion of the rise of normative participation in science and technology. Finally, this thesis will frame local knowledge in terms of how it can practically contribute to risk assessment.

First signs of local knowledge

The first signs of a local knowledge theory arrived at a time when decisions over complex technologies were beginning to be made (Fischer 2000, p.6). In the wake of the development of large-scale industrial societies, some theorists began to study the role the public played in decisions which involved increasingly complex technical problems (Irwin 1995, p.10). Dewey (1927) noted that the majority of the public had no understanding of how everyday objects that they were using actually operated in terms of their technical design. As a result decisions over complex technologies were not open to the general public. This, concluded Dewey (1927), was a significant problem facing public participation and democracy in general, particularly as lack of participation left citizens open to political manipulation and susceptible to populist politics such as fascism. In order to resolve this, Dewey proposed that the role of the public and experts be separated. Experts would identify the social issues and citizens would politically pursue the needs and problems. The two processes would combine through debate, in which experts would not participate in any normative judgement but act as interpreters and analysers (Dewey 1927).

Although Dewey's theory arrives at a conclusion that legitimates experts' superiority in assessing complex decisions, a conclusion many local knowledge writers now seek to dismiss, his book did highlight the two common questions in the local knowledge literature: how can the public participate in complex decisions? And, why does the public not participate?

These questions lead to an inevitable discussion of what the nature of local knowledge is and, in turn, how this can make a meaningful contribution to complex decisions. As

stated at the beginning of this chapter, local knowledge in itself is an ambiguous term and different theorists have emphasised different parts of its nature (Antweiler 1998; Antweiler 2004; Agrawal 1995). The next part of this literature review will discuss the themes associated with the concept of local knowledge, after which an exploration and critique of current methods of public participation will be explored in the context of local knowledge literature.

General themes of Local knowledge

Lindblom and Cohen's 1979 book *Usable Knowledge* (Lindblom & Cohen 1979) offers a useful beginning point for a description of local knowledge. The authors were interested in how professional social inquiry was performed and why such inquiry, in their opinion, often produced predictable and poor results. Professional social inquirers are the equivalent of policy makers or what is termed 'experts' today; they would study and attempt to solve seemingly 'complex' social issues. The perception professional social inquirers had of the nature of work they performed and knowledge they held was considered the reason for their failures. The authors believed that professional social inquirers considered themselves the only qualified group to solve social problems. They greatly overestimated the speciality of the information and analysis they used in problem-solving. Cohen and Lindblom argued professional inquiry by experts was only one of several avenues to problem-solving. Using what they identified as 'ordinary knowledge' was another useful tool in solving social problems.

'Ordinary knowledge', as described by Lindblom, is knowledge that owes its origin to "common sense, casual empiricism, thoughtful speculation and analysis" (Lindblom & Cohen 1979, p.12) and is knowledge not exclusively held by experts. It is described as what we all know through everyday observation. Thus, ordinary knowledge is equivalent to common knowledge.

As this knowledge is based on everyday observation, experience becomes an essential component to its development, a characteristic vital to descriptions of local knowledge. Lindblom and Cohen argued that as ordinary knowledge is accessible to everyone, professionals waste a lot of time studying what is already known. If this type of knowledge were incorporated into problem-solving, professionals would be

free to focus on more complex areas of the problem and would use their resources and time more effectively. However, whilst some claim that local knowledge is more commonly shared than scientific knowledge (Brush 1996), others have claimed that local knowledge is more specialised than the concept of ordinary knowledge allows for (Breyman 1993).

Local Knowledge: More specific than common

Breyman (1993) suggests that local knowledge is similar to ordinary knowledge, yet site-specific (Breyman 1993, p.131). Like ordinary knowledge, local knowledge is often developed through everyday observation and analysis, however it is not universally held throughout society. As Antweiler (2004) suggests, local knowledge is a product of universal human capability, but is situated within a specific contextual environment. It is knowledge that is relevant to particular experiences, often, but not exclusively, related to a particular locality. Local knowledge is thus often not “common” knowledge.

Interaction within an environment

Another important theme within the literature of local knowledge is interaction within a particular environment. Gladwin (1989) suggests that farmers develop adaptive skills through years of experience and cultural tradition that “have coevolved with local environments” (Fischer 2000, p.201). Van der Ploeg (1993) describes the local knowledge of Andean potato farmers. In selecting seeds, the farmers study the immediate environmental conditions such as climate and land considerations, whereas scientists work from an idea of an ideal seed (Fischer, 2000, p.204) and test this in standardized conditions.

Schmidt’s (1993) description of the experiential knowledge acquired by workers filling a reservoir on the Tonton River, Idaho, in the US illustrates a number of aspects of the importance of the knowledge acquired through interaction with the environment. This work led to the collapse of a dam and the killing of eleven people (Schmidt 1993, p.525) largely because, Schmidt suggests, experts made safety decisions whilst ignoring the experiential knowledge of the grouters. The workers would grout holes; however as grouting was not an exact science, many of the workers’ decisions were based on experience and intimate interaction with the

environment. As Schmidt suggests “the art of grouting appears to require continuous attention to a host of subtle qualities” (Schmidt 1993, p.526), and these qualities cannot be analysed outside of the context upon which they are occurring. The knowledge of how to adequately grout holes is built upon over time, as each hole will contain different variables that will affect how the mix of grout should be applied. This knowledge is what Schmidt describes as a ‘feel for the hole’. As Schmidt (1993) suggests a tacit development of this knowledge through ‘strategies’ designed to deal with the environment over time, it can be argued that the knowledge is not fully conscious or easily describable. In this sense, Schmidt illustrates that local knowledge is not measurable nor easily “subjected to rules or standards”(p.526).

Schmidt also describes the fragmented nature of knowledge which, if put together, can form more of a complete understanding of a matter. For example, grouters knew about the holes, whereas engineers working on the base of the dam held knowledge of the irregular surface of the rock they were working in. Thus, within one project there are different areas of knowledge and expertise that must be considered. Schmidt describes this collective knowledge as a ‘feel for the whole’.

A third form of knowledge is passive/critical knowledge which workers held. Thus, workers were able to question why work on the dam stopped early, assuming it was because pressure at the top of the dam was lesser than at the bottom, and thus they had reached a level at which it was safe to stop. Unfortunately, the real reason for stopping was budget constraints; pressure at the top of dam was not taken into consideration. As a result the dam collapsed and lives were lost. Therefore, through an intimate interaction with their given environment each worker held knowledge that was useful to the overall safety of the project. Schmidt suggests by combining this knowledge, disasters may potentially be avoided.

Wynne's (1996; 1992(a); 1992(b)) study of hill sheep-farmers of the Lake District of northern England who were confronted with contamination from the 1986 Chernobyl accident is another example of how experiential, environmental and contextual knowledge is important and different from purely technical approaches. Wynne illustrates how the farmers held important knowledge regarding their environment, social processes under which they operate and the ability for scientific testing to adapt

to these factors. For example, farmers were asked by scientists to test a product that aimed to help avoid recontamination of animals from grazing. In order to test the product, sheep were required to be fenced in on “contained fell-side plots” (Wynne 1996, p.26). Some farmers suggested that because the sheep were used to roaming over open tracts of fell land, fencing them in would invalidate the experiment by tending to make the animals lose condition. Initially, this concern was ignored by the experts; however the experiment was later abandoned for the exact problem the farmers had identified (Wynne 1996, p.26).

Beyond physical experience

The above examples are based around experience within a physical location, and often agricultural climates are used as a main case study for local knowledge (Wynne 1996; Ploeg 1993; Hess 1997; Neufeld & Cinnamon 2004). However, as noted earlier, local knowledge does not necessarily relate exclusively to a physical location. An important aspect already identified is experience in the development of this knowledge. Thus, local knowledge can equally apply to experience in given situations and practices rather than locations (Antweiler 2004; Lave 1993; Nygren 1999). This is often called situated knowledge, but has its base in experiential and contextual forms of knowing. As Raffles (2002) suggests, the locality in local knowledge is formed through the sharing of ideas and relational practices, and is not exclusively formed from a physical location.

Beyond communally and traditionally held knowledge

It is important to note that because of the relational and situated nature of local knowledge, certain knowledge may not be shared universally within a community. Some have criticised the tendency for local knowledge to be romanticised as a commonly shared unique knowledge within an isolated community (Nygren 1999; Raffles 2002). This is particularly the case for anthropological accounts of indigenous or traditional knowledge (Nygren 1999). Nygren argues that many anthropological studies are concerned with traditional knowledge held within “intact cultures” (Nygren 1999, p.270), rather than the hybrid forms of knowledge developed in diverse societies. Accounts have illustrated that, within communities, knowledge is not held universally as some individuals are considered to have more expert information than others (Davis & Wagner 2003).

In her study of the local interpretations of expertise within the Isle of Man community, in relation to ionising radiation, McKenchnie suggests that locals within a community recognise that some hold more practical knowledge than others, given their day-to-day experience with the relevant issue. For example, fishermen were considered most knowledgeable in the effects of radiation on the fishing industry within their community (McKechnie 1996, p.134). This illustrates further that local knowledge is defined mostly by its contextual placement, not by its traditional homogeneity. Therefore, within communities different forms of knowledge can be identified.

Adaptability

Another important aspect of local knowledge is its adaptability. As it is based on experience coping with changing local conditions, the ability to adapt to environmental changes and uncertainty has often been stressed by local knowledge writers (Wynne 1996; Gladwin 1989; Antweiler 1998; Chambers 1981). Thus, unlike traditionally scientific forms of knowledge, which often work off standardized concepts, local knowledge is argued to be more accepting of complexity and variation in factors affecting decisions. Wynne (1996) illustrates the adaptable nature of local knowledge compared to the standardized approach of scientific research and argues that whereas local members of the public are willing to utilise technical knowledge in their everyday lives, those using technical approaches were less receptive to local forms of knowledge. This is ironic given that local knowledge is sometimes associated with traditional and unreflexive forms of knowledge (Nygren 1999; Raffles 2002), while modern science has been described as open and reflexive. The next section will discuss local knowledge within the context of the public understanding of science literature.

Public Understanding of Science and the Deficit Model

Local knowledge, although ill-defined, has been implicated in discussion of public trust and participation in matters of science and technology. Many scholars, and policy makers, have begun to call for more public participation in complex matters. Recently the science community has also sought to encourage public involvement in decision making (Stern, Fineberg & U.S National Research Council Committee on

Risk Characterization. 1996; The House of Lords Select Committee on Science and Technology 2000).

This marks a change from the commonly held perception within the risk assessment agencies that decisions over science and technology should remain within the domain of experts. This development within the science literature is perhaps a reaction to revelations that science itself is not trusted or understood by the 'public'. Debates over issues such as the BSE crisis in Britain during the 1990s, or genetic engineering world-wide, have illustrated the differences between the outcome of "expert" risk assessment and decision-making and the attitudes the public holds on such matters, as well as a widespread lack of trust in experts (Jasanoff 1997). On the back of such negative responses, the science community and many social scientists began to question the reason for such an unexpected divide between the public perception of science and the perception science held of its own role in research and decision-making (Irwin & Wynne 1996; Yearley 2005; Dierkes & Grote 2000). Although interdisciplinary, this focus has formed a literature which is known as the 'public understanding of science' (Sturgis & Allum 2004).

The initial attitude from many within the science community was that the public generally did not understand complex scientific issues, and thus their ignorance leads to negative responses (Irwin & Wynne 1996). Survey questionnaires and quizzes that have focussed on what the public know in relation to scientific truths are common within the study of public understanding of science, and seek to support the belief in public ignorance. For example the public knowledge of facts pertaining to biotechnology have been tested (Marlier 1992), as well more general understandings of science (Durant, Evans & Thomas 1989). These questionnaires generally conclude that there is a certain amount of ignorance within the public pertaining to basic scientific fact (Irwin & Michael 2003, p.22). In order to improve the relationship between science and the public it was therefore considered appropriate to educate the public on scientific and technical matters. For example, the British Royal Society report in 1985 asks and answers in the affirmative, "Would the world be a better, or even a different, place if the public understood more of the scope and the limitations, the findings and the methods of science?" (Great Britain. Royal Society Council. & Bodmer 1985 cited in 'Public Understanding of Science: The Royal Society Reports'

1986). The process of education in the views of the science community would dissipate public fears of risks associated with new technologies, and in turn instil confidence in scientific research.

Wynne has described such an understanding of public mistrust and disagreement as a 'deficit model' (Wynne 1992(b)). The main assumption of the deficit model is that attitudes toward science generally correspond with the level of knowledge held by the individual. The more an individual understands the basic tenets of scientific research the higher the level of acceptance will be. Taking this angle further it is suggested that in order to participate in decisions involving complex data, the public must hold a basic understanding of this data.

Critiques of the Deficit Model

Several writers have critiqued this approach to understanding public knowledge of science and the role of public participation (Irwin & Michael 2003; Irwin 1994; Wynne 1996; Irwin & Wynne 1996). Irwin and Michael (2003) argue that questionnaires designed to test public knowledge are fundamentally flawed. Several writers have argued that questionnaires are designed not to elicit local knowledge in order to improve scientific technique and understanding, but are designed to illustrate the lack of knowledge the public holds (Yearley 2005, p.119). The questionnaires upon which much of the research is based generally hold the participants' grasp of scientific 'facts' as the ultimate measure of scientific knowledge, where several other answers from participants may illustrate knowledge that remains unmeasured. The assumption that formal scientific technique is the only avenue to meaningful information is therefore inherent in this approach, particularly as the questionnaires do not take account of whether someone disagrees with a commonly held scientific belief, or genuinely is unaware of what the belief is (Yearley 2005). Evan and Durant's (1995) research suggests that citizens with a good grasp of scientific knowledge are often more sceptical of some scientific claims in relation to morally controversial research (Evans & Durant 1995 cited in Sturgis & Allum 2004, p.59). This point has been supported by Eurobarometer surveys that suggest some regions that are more knowledgeable about GMOs are less supportive of its implementation than those with less knowledge. For example Northern Europe generally holds more knowledge than Southern Europe about GMOs but tends to be more outspoken in

opposition (International Research Associates (INRA). 2000 cited in Hallman 2000). Thus, the premise that more scientific knowledge will translate into better acceptance is contradicted by these findings.

Sturgis and Allum (2004) criticise the deficit model because it values only one form of knowledge that lay people may hold. Although the authors agree with the assumption that attitudes are linked to knowledge, testing the public's scientific knowledge ignores the complex and interactional knowledge held by individuals, and how this knowledge also interacts with the attitudes of the public. Thus, as science is embedded within social and political frameworks, the publics' understanding of policy and social structures surrounding science will affect attitudes. The authors then illustrate how surveys can test and encompass both contextual knowledge and traditionally scientific knowledge.

Likewise Wynne argues that the extent of scientific 'textbook' knowledge is but one area that influences the public's attitudes. Wynne suggests that three elements of public understanding are needed in order to understand the connection between knowledge and attitudes. These are, "formal contents of scientific knowledge; the methods and processes of science; and its forms of institutional embedding, patronage, organization and control." (Wynne 1992(b) cited in Sturgis & Allum 2004, p.58). Therefore, the public uses scientific knowledge in the context of other factors, including other forms of knowledge which will also affect their attitude towards traditional scientific knowledge.

Criticism of the deficit model marks a difference from the perception that the public must change; rather it suggests that the scientific approach should adapt to the contextual situation in which knowledge is applied. In this way, social scientists seek to understand why the public does not trust experts from a different angle than the deficit model.

Irwin's *Citizen Science* (1995) argues that science acts improperly as a device for legitimating political values, rather than a tool for empowering the citizen. Legitimation of certain policies is built by using 'expert' opinion as endorsement.

Irwin suggests that science therefore does not seek to help citizens but is used by policy makers to gain political leverage. This leads to a cynical outlook from citizens.

However, more importantly for the current thesis, several social scientists have suggested the reason for the poor relations between the public and science is that science does not recognise that the public holds any relevant knowledge about technological matters (Wynne 1996). This argument is often offered as a critique to the deficit model, similar to Wynne (1992) illustrated above. Sturgis and Allum (2004) call such arguments the ‘contextualist approach’. Irwin and Wynne offer a series of case studies addressing this issue (1996).

Several writers have connected the lack of trust in experts in relation to how experts recognise local knowledge (Jasanoff 1997), or can adapt their own knowledge into the frame of local knowledge and local context (Neufeld & Cinnamon 2004; Ozonoff & Boden 1987; Fischer 2000). Fischer (2000) suggests citizens turn to their own “cultural rationality” when they do not trust experts. “Cultural rationality” is concerned with the importance of personal experiences in assessing risk. Unlike questionnaires in which knowledge is assessed outside of any context (Yearley 2005), cultural rationality is used to assess scientific claims within one’s experiential context. Thus, “cultural rationality” is employed to assess expert claims. In this way, arguments about “cultural rationality” and local knowledge are often based on the common observation that citizens lack trust in experts and that trust can be increased through the recognition of local knowledge in technical decision making.

The important division, however, lies in the question of whether the lack of trust itself is seen as the problem, or a lack of trustworthiness on the part of experts is the problem. If the lack of trust is regarded as problematic, then therapeutic solutions that focus on building better public representation may be called for. If it is the trustworthiness of the experts that is viewed as the problem, a greater scrutiny of the usefulness of expert knowledge and its influence over policy making will be called for.

Normative participation in scientific matters

Although the focus on educating the public remains within science-based literature, there has also been a movement toward encouraging the public to participate in normative assessments of scientific decisions, perhaps as a response to the high level of criticism the deficit model has attracted. Many councils and government bodies have been set up to allow an avenue for public opinions and values to be heard in relation to technological decisions. For example, in New Zealand The Bioethics Council was formed in 2002 as a Ministerial Advisory Committee, following “a recommendation by the Royal Commission on Genetic Modification, to meet public concern that decision-making was not adequately addressing the ethical, cultural and spiritual dimensions of genetic modification and biotechnology” (The Bioethics Council (b)). The Bioethics council holds public ‘conversations’ about issues surrounding biotechnology whilst also making recommendations to the government based upon public discussion over such matters.

A recent example of such conversation is the dialogue surrounding xenotransplantation, the transplantation of living cells or organs from one species to another. Forums were open to the public in the major cities, and a dialogue over the internet was set up for people to participate. Other governments around the world have similarly begun to encourage public involvement in decisions over the normative aspects of a technology. A report in March by the 2000 House of Lords Select Committee on Science and Technology (CST) in England suggested that development of mistrust has occurred because decisions are only discussed in terms of technical matters, and thus serious social, cultural and economic implications are ignored (House of Lords Select Committee 2000). Therefore, the report recommended more openness to public involvement in normative areas of technology policy. Wilma Aarts describes the Dutch public debate on the genetic modification of animals, and attempts to include the public through a “consensus conference”, in which “lay people have a central role in the discussion and the assessment of a technology. (Aarts 1999)”. It has been documented that similar conferences have been held in twelve other countries⁶, including New Zealand, the majority dealing with decisions over gene technologies (Goven 2003)⁷.

⁶ The Loka Institute documents that these countries have held consensus conferences: Argentina, Australia, Canada, France, Germany, Israel, Japan, the Netherlands, New Zealand, Norway, South

Such developments in public involvement in technology mostly occurred in response to criticisms of the representation of scientific decisions as value-free. In fact, many studies have shown that ‘scientific’ decisions are neither value-free, nor devoid of social implications. Examples within the literature show evidence that suggests scientific findings have been misrepresented or suppressed in the favour of some interest groups (Stern, Fineberg & U.S National Research Council Committee on Risk Characterization. 1996). Rosner and Markowitz (Rosner & Markowitz 1985) explore the case of lead poisoning from gasoline that can be traced to the period of the 1920s in the United States, but only became widely controversial in the 1970s. According to the authors, evidence linking health problems to the gasoline product was often not publicised due to corporate pressure. After such findings show the falsity of value-free claims, it is no surprise writers suggest that there is a mistrust issue (Stern, Fineberg & U.S National Research Council Committee on Risk Characterization. 1996). As the decisions also have social effects, it is thought that the public should have input into whether such effects will be positive in relation to their own values and opinions.

Meanwhile, several governments appear to have begun to interpret negative public reception of science-related decisions as due to public relations problems rather than any public ‘deficit’. Science and government policy makers now generally recognise the importance of understanding public attitudes in order evaluate risk, as illustrated by the number of opinion polls that are now conducted (Weale 2002). It is perhaps for this reason a large number of studies on public attitudes to new technology and what affects these attitudes, particularly in relation to genetically modified organisms, can be identified in New Zealand (Coyle & Lincoln University (Lincoln N.Z.). Agribusiness and Economics Research Unit. 2003; Hunt et al. 2003).

Practical participation, beyond normative participation

Unfortunately, the ability to contribute normatively often limits or overshadows the chance of alternate forms of expertise, outside the sphere of science, to be recognised

Korea, Switzerland, Britain, and the US (<http://www.loka.org/pages/worldpanels.htm> cited in Goven 2003).

⁷ On consensus conferences, see Andersen, I.E. and Jaeger, B. (1999).

in public participation (Levidow and Carr 1997). As writers who address local knowledge have argued, the sphere of value claims is only one area in which the public can participate: they can also contribute practically to decision making. However, the public is often, intentionally or not, marginalised within the arena of normative participation, which implicitly suggests that the science community has reached a level of certainty at a technical level, and therefore, needs no contestation⁸.

A represented dichotomy between scientists and the public, scientists being equated with 'expertise' and public with 'values' is apparent within efforts to increase public participation. For example, Goven (2003) notes that at a New Zealand consensus conference a theoretical biologist nominated by Greenpeace to speak, and who voiced concerns over plant biotechnology for reasons beyond the purely technical, was identified as "nominated by Greenpeace", whereas other scientists had their nominators unidentified. In later discussions panellists "recall him as a "greenie," rather than a scientist." (p.439). It can be assumed that the inversion of the assumption by panellists, that scientists hold their expertise only in the technical arena, is that the public should restrict their views to the arena of values.

It is also important to note that some writers have identified that the new-found focus on public opinion and values is in line with the commercial concerns of the technological sector, which wishes to gauge the commercial viability of new technologies, essentially limiting public participation to that of a consumer (Davison, Barns & Schibeci 1997). Therefore, although attitudinal studies may allow participation for the public in terms of expressing values, there is still a lack of genuine recognition of local knowledge as something that could practically benefit analysis of problems and risk assessment.

This distinction highlights the difference between normative, substantive and instrumental arguments for participation discussed by Fiorino, which illustrate the literature discussed so far (Fiorino 1990). In his discussion of citizen participation in

⁸ The House of Lords Select Committee on Science and Technology 2000 does recognise this point, "The Institute of Science in Society suggests another, less obvious danger: that, if the divide between expert and lay members is too clean, 'that implicitly assumes that the science has been established beyond any doubt, so that all that remains to be discussed are the ethical, environmental and other such issues'" (The House of Lords Select Committee on Science and Technology 2000, p. 330). However, focus does remain mainly on a normative argument for participation rather than an instrumental one.

environmental risk assessment, Fiorino suggests that participation is normatively important for the development of democracy, but he also recognises instrumental and substantive arguments. The instrumental argument is that allowing participation will decrease conflict and increase trust in experts. The substantive argument posits that useful knowledge exists outside of purely scientific circles. Therefore by using local knowledge better decisions can be made by risk assessors, both substantively and normatively.

Popular Epidemiology

Several strands of literature have demonstrated that the public can contribute to practical solving of problems in a variety of ways. The literature on popular epidemiology is one area which offers good examples. Coined by Brown after his study on Woburn, Massachusetts, popular epidemiology can be defined “as the process by which laypersons gather statistics and other information and also direct and marshal the knowledge and resources of experts in order understand the epidemiology of disease”(Brown 1987, p.78). This has been mostly discussed in relation to public participation in issues surrounding toxic waste. The literature explores the difference between local and expert ways of knowing and the contrasts between the definitions of problems, the perceived significance of statistical findings and the implications for policy (Shavelson 1988 cited in Brown & Mikkelsen 1997; Brown 1992; Ozonoff & Boden 1987).

For example, Brown describes the process by which members of the small community of Woburn, Massachusetts (USA) identified and fought for scientific recognition of a cluster of leukaemia and health problems linked to the contamination of the water supply by two factories in the district. As the community was relatively small, traditional scientific procedures did not recognise local discovery of common ailments as statistically significant and therefore the risk of the factories’ toxic waste was not recognised in policy. Ozonoff and Boden (1987) illustrate the difference between statistical significance and public health significance, where a cluster that may be of little statistical significance due to the small number of people within the supposedly contaminated zone is however of a high public health significance to those within the zone. Therefore, popular epidemiology not only illustrates how local knowledge can recognise risks within a community, but also that current risk evaluation procedures

are not designed to acknowledge the contribution of local knowledge – or identify all significant health risks. This can be because of the view that science is the ultimate judge of risk and the public is emotionally biased (Brown 1992; Brown & Mikkelsen 1997), types of statistical methods adopted (Ozonoff & Boden 1987), or the different priorities of community members compared to those in positions of economic and political power (Nash & Kirsch 1986; Ozonoff & Boden 1987).

The identification of a cluster begins through techniques that fall in line with the earlier description of local knowledge. Casual observation deriving from a particular context and experiences (Brown & Mikkelsen 1997) identify issues that scientific approaches were not designed to be able to pick up. For example, Brown illustrates the beginning stages of identification in the Woburn, Massachusetts leukaemia cluster.

Anne Anderson, whose son, Jimmy, had been diagnosed with acute lymphatic leukaemia in 1972, had gathered information about other cases by word of mouth and by chance meetings with other victims at stores and at the hospital where Jimmy was being treated. (Brown 1987, p. 79).

Locals also had identified a strange smell and taste in their water supply; this would later be linked to what became identified as a disease cluster. Thus, individuals who held experience in everyday dealing with disease and the local factories held valuable knowledge, and expertise, on the causes of the cluster that could not possibly have been identified through traditional scientific statistical methods.

Other case studies on popular epidemiology support Brown's findings (Brown & Mikkelsen 1997). Nash and Kirsch (1986) describe the identification of occupational health problems in a General Electric Plant and environmental degradation caused by the plant located in Pittsfield, Massachusetts, USA. Members of the community, such as fisherman, recognised a problem whilst observing the large amount of dead fish and missing small animals. Nash and Kirsch call for recognition of community research in risk assessment of toxic waste.

Others have addressed the case study of Love Canal (Ozonoff & Boden 1987; Levine 1982) in which locals noticed various phenomena including unusual numbers of miscarriages. The New York Department of Health investigated claims by locals that miscarriages were unusually common in areas surrounding Love Canal, however they only studied miscarriages verified by hospital or physicians in Love Canal, whereas their research of the comparison group addressed all miscarriages (Ozonoff & Boden 1987, p.70). The results of the study were therefore statistically inaccurate. This illustrates both the inability of expert methods to incorporate local knowledge and experience, and also the uncertainty and potential for human error in traditional scientific methods.

Popular epidemiology examples illustrate that lay members of the public can contribute practically to scientific knowledge and understanding, and to the assessment of risk. As illustrated, popular epidemiology efforts have exposed a range of dangers; according to Brown, these include “DES [diethylstilbestrol], Agent Orange, asbestos, pesticides, unnecessary hysterectomies, abuse of sterilization, black lung disease, and brown lung disease (Brown & Mikkelsen 1997,p.133)”. Popular epidemiology has also illustrated the limitation of some scientific epidemiology procedures. However, popular epidemiology highlights cases where popular knowledge must be translated into scientific knowledge before it can become part of a policy or assessment process. Although initial identification of clusters occurs through casual observation and experience linked to local knowledge, the language of participation still remains that of the expert, for example, pertaining to methods of recognising statistical significance (Brown & Mikkelsen 1997; Lagakos, Wessen & Zelen 1986). Indeed, the community typically is listened to only when so-called “counter experts” take up the community’s cause. Thus, the public only gains recognition when they are able to appropriate recognised scientific forms. This illustrates the reliance on experts for participation discussed by others in literature regarding the concept of a risk society (Giddens 1990; Beck 1992). Moreover, the assessment of the risk occurs after a technology has been released into the community, in which case the damage has often already occurred. The literature lacks a discussion of how local knowledge can contribute to prediction of future risk, before a technology has been implemented. Such participation requires an active role for the

researcher in order to identify who holds relevant local knowledge before the technology has been imbedded within a community.

Local knowledge and risk assessment

Risk assessment has its roots in epidemiology (Slovic 1999, p.44). Popular epidemiology illustrates that local knowledge and observation is useful in detecting clusters of disease and illness. Much of the literature on local knowledge suggests that it can be useful in the recognition of other risks as well, including social, environmental and economic risks. It can also point out the limitations of traditional risk assessment and areas that need improvement (Wynne 1996; Krimsky & Plough 1988). Therefore, a number of scholars have attempted to illustrate how local knowledge can complement risk assessment, essentially because risk assessment involves assumptions about how social networks operate.

In *Citizen Science: A Study of People, Expertise and Sustainable Development* Alan Irwin suggests that the idea of social knowledge contributing to technical understanding of risk assessment is often resisted by the science community, as it breaks the rule of having science separated from societal activities (Irwin 1995). It is on this premise of separation that modernity as a social structure and scientific advance has been built. Likewise Bradbury suggests, “[b]y virtue of their frames of reference, technical managers are predisposed to adopt technical approaches to risk management. (1989, p.388)”. Hays (1987) suggests that complexity of issues mean that scientists now generally study in one field (Hays 1987, p.343), becoming emotionally invested in their field, and hence motivated to see that it is recognised as the informative source on a matter. The need to have the ‘right’ answer has politicised science into a competitive market of ideas. This has encouraged limited, not open, world views, in which the incorporation of various types of knowledge is discouraged. Thus technical managers are able to develop technology away from any thought of its social implications.

However, the understanding of science as socially unbiased is inherently flawed. Science-based risk assessment involves assumptions about the nature of the social world and value choices (Yearley 2005; Irwin & Wynne 1996). This is evident in the process of identification and estimation of risk on one hand and evaluation on the

other, when the separation of such tasks is impossible (Bradbury 1989, 381; Wynne 1980). The process of identification involves an inherent evaluation of a subject. By estimating and identifying a subject, one is also categorising its nature and therefore already making a social or value-laden decision. That is, in order to determine what constitutes risk, one must assume that what is threatened by that risk is of value. Therefore both identification and quantification of risk have in-built normative principles.

Wynne (Wynne 1988) also suggests that it is social practices that define the rules of how a technology is used; therefore, it is not the technology itself which defines its use. Criticism is levied at risk assessment processes which ignore the social dynamics within which a new technology will operate. Haraway (1991) argues that one's position is fundamental to the development of knowledge. Therefore, whereas early works have stressed the importance of a technical understanding of science, in which its values and assumptions are tacitly accepted, new writers have stressed the importance of a social understanding of science (Irwin & Wynne 1996). That means an understanding in which the implications of a technology are understood in context of the public or 'lay persons' everyday life. Therefore, local knowledge literature suggests that knowledge is situational in nature. If this is the case, the idea of science as an ultimate and purely technical judge on complex matters is challenged.

Several case studies have supported this point. For example, during the BSE crisis, recommendations of how to remove potentially contaminated cow body parts illustrate the expert lack of knowledge about processes in and assumptions about the social workings of slaughter houses, which consequently made recommended procedures impossible to follow (Yearley 2000,106; Jasanoff 1997). Wynne (1996) has argued that as scientific inquiry makes social assumptions, local knowledge is more helpful than scientific expertise in some areas. In this way, local knowledge is a valuable source of information, and a way to avoid flawed social assumptions within risk assessment and regulation. In order to recognise local knowledge within risk assessment, a general change in how risk is defined is needed. Risk is not only a technical matter, but is contingent upon social processes.

Risk Conceptualisation

The characterisation of what risk entails is important in decisions of who will be involved in risk assessment (Stern, Fineberg & U.S National Research Council Committee on Risk Characterization. 1996). Therefore, characterization, or definition, of risk should occur before an analysis of risk occurs. Although this seems rather intuitive, it has been illustrated that risk analysis often occurs before any consideration of what the character of the risk is. Although the character of risk is always decided upon before risk analysis, it is rarely acknowledged that the decision has occurred. This is illustrated by the fact that risk assessment and risk management are sometimes separated within the literature. Risk assessment is suggested to be scientifically and objectively based, whereas 'risk management' weighs risk against other issues in order to make decisions about risk control (Levin & Strauss 1991), leaving more room for societal and value based considerations (Busch et al. 2004). Under this distinction, societal concerns are only included after the risks have been identified by experts. Therefore, risk analysis implicitly relies on assumptions from experts about who is likely to be affected by a new technology, and also how they will be affected. Such assumptions lead to faulty recommendations as stated above. The separation of risk assessment and risk management also leads to misleading representations of the certainty of risk assessment (Busch et al. 2004; Silbergeld 1991).

Judith A. Bradbury (1989) identifies two types of risk conceptualisation that reflect the criticisms of current risk assessment, 1) risk as a physical problem caused by hazardous technologies and 2) risk as a socially constructed attribute. Likewise, Funtowicz and Ravetz (1985) identify two dimensions in social problems, factual and valuative dimensions, or as they term them, systems uncertainty and decision stakes. The systems uncertainty stake measures how much factual information is known about issues surrounding the decision. Decision stakes measure the level of consequence that is associated with a decision. These consequences relate to valuative issues, such as the level of controversy a decision will attract. Both factors, systems uncertainty and decision stakes, can be assigned a low, medium or high level. If both dimensions are low then it is likely that a technical approach is acceptable. The decision will not be controversial to society and there will be a high level of information obtained to counter disagreements within the science community. However, if both dimensions are high then a purely technical approach will be

inappropriate. That is when the information is not well documented and the social implications are likely to be high. The authors suggest the role of the public should be to act as an extended peer community in which technical decisions are critiqued in these situations.⁹

Yearley (2000) critiques this model because it assumes that the stakes of a decision can be easily agreed upon. Various studies have shown that perception of a decision's importance is often contested (Slovic 1999; Bradbury 1989). This is supported by Irwin, who argues that the "literature on risk assessment suggests perceptions of risk and hazard may serve as a focus for a whole array of doubts and uncertainties about the direction of social change" (1995, p. 40). This is illustrated for the inverse situation in research by Slovic (1999) that suggests people view x-ray technology as low risk because they trust the processes used to contain the risk. Therefore, risk assessment is also linked to public perception and trust in science and risk management.

Krimsky and Plough (1988) contrast the concept of technical rationality with the idea of "cultural rationality" in risk assessment. Technical rationality focuses on traditional scientific method, that is, expert judgement and empirical evidence to assess risk. "Cultural rationality" is concerned with the importance of personal experiences in assessing risk. Concerns are not only technical and empirical in nature, but assess the circumstances under which the technology will be implemented. "Cultural rationality" therefore places the social impact and implications of a new technology within the sphere of risk (Brown & Mikkelsen 1997, p.178). Therefore, risk is based upon one's own rationality, in which case risk is essentially contested by different rationalities. Risk assessment that entails conceptions of both social and technical areas of risk is therefore important.

Bradbury (1989) suggests a cultural approach to risk assessment. The cultural approach allows for the use of social knowledge for critical as well as for instrumental purposes. Social knowledge can help facilitate creative solutions to policy problems,

⁹ Some have critiqued the presumption of a single scale uncertainty measure, particularly as there are various forms of not knowing ignored in such an approach (Jasanoff, S. & Wynne, B. 1998, cited in (Yearley, 2000 p.108).

as well as fulfilling the critical purpose of contributing to defining of the policy problem itself. This approach offers a critique of traditional forms of policy making and risk analysis, which is based upon the conception of risk as being solved through purely factual considerations. Therefore, like Irwin in *Citizen Science* (1995), Bradbury suggests that better policy is not only created through an improvement in technical process, but through an acknowledgement of risk as a social and value-laden entity, and by developing a framework for meaningful dialogue between holders of different values and knowledge on risk. Thus, discussion of risk is based upon the wider discussion of the role of science in society.

Like the literature on popular epidemiology, studies of the role of local knowledge in risk assessment have mainly involved case studies that illustrate the failure to take local knowledge into account. A large part of this literature emphasises the problem in the light of public understanding of science and the effects this has on the public's attitude toward the science community. Therefore, while the studies do illustrate the ability of local knowledge to help risk assessment practically, it is not the main focus of the literature. There is a lack of studies illustrating the use of local knowledge to assess the risk of a technology before it has been implemented or disseminated within society at a practical level. This study will involve identifying potential areas of social expertise perhaps even before the holders of such knowledge are aware of its usefulness.

A Pragmatic approach to Local Knowledge

It is important to note that not all local knowledge is helpful or useful to problem solving, or even to those who hold the knowledge (Less 2000; Hess 1997). Hess (1997) describes the local knowledge of some sheep farmers that actually harms sheep and produces poverty, whilst the author also claims its inherent worth (Hess 1997 cited in Less 2000). As stated earlier the tendency to romanticise local knowledge has been documented in the literature. Nygren (1999) argues that this mystification of local knowledge essentially excludes local knowledge from any rational contribution to decision making. Although local knowledge is viewed as an important avenue to freedom for indigenous people, it is also represented as incompatible with real science in its 'ancient wisdom' (Nygren 1999). This can exclude indigenous people from

practical participation and also means that non-indigenous people with useful knowledge are often excluded from decision making (Nygren 1999).

Vayda, Walters and Setyawati (2004) suggest that local knowledge is exaggerated in the context of what it can do to improve economic development and environmental conservation. This mystification is caused partly by the methods taken to study local knowledge outside from any contextual situation. Local knowledge is often studied in isolation from any practical problem, particularly within the anthropological field (Vayda, Walters & Setyawati 2004, p. 39). Therefore, by studying the knowledge isolated from any contextual relationship the knowledge is simplified. The authors argue that local knowledge should be studied in relation to a specific event or actions, in terms of what actors know that can help develop better understanding of the action or event being studied. This method would demystify local knowledge as well as offer a practical contribution, without getting held back by the study of complex systems of knowledge within the whole of a given community or society.

Conclusion

The literature has described local knowledge as experiential, adaptable, situational and relational. Local knowledge is not exclusively held by a limited number of cultures; individuals and communities within society may hold unique information about their social and physical environments. The current thesis suggests that in order to better assess the risks of animal biopharming, it is vital to adopt and use local knowledge that has been acquired by individuals and communities through their experience and relationships within their own social environment, with which animal biopharming will interact.

Therefore, the social risk of animal biopharming can take two forms. Firstly, there may be a risk of animal biopharming to valued social practices that may be influenced by its introduction. Secondly, and perhaps more relevant to this particular thesis, social practices may shape the nature of the risks posed by animal biopharming itself. It is difficult to make a measured decision about the risks of animal biopharming without understanding intimately how the technology and its regulation will fit within its social context. Local knowledge of how these social practices are performed

outside of the general theorization and abstractions of traditional risk assessment is vital.

It is this latter approach to local knowledge that is adopted here. Unlike most of the literature, this thesis is less concerned with how local knowledge can influence the relationship between science and society, but more with how local knowledge can help make better decisions about technology. It is pragmatic in the sense that local knowledge is explored mostly in terms of whether and how it can be used to improve the risk assessment process, particularly in relation to animal biopharming in New Zealand¹⁰. Local knowledge in this sense can be of an instrumental value to identifying risks before they occur, rather than merely an indicator of the complexity of public attitudes towards science.

¹⁰ Several writers have illustrated the value of local knowledge in relation to the identity of individuals and communities (Wynne 1996; Irwin 1995) . In this sense a normative consideration of local knowledge should be, and has begun to be, included in decision making over complex decisions. Local knowledge in this context relates to traditionally held values, beliefs and practices. In terms of the discussion above, local knowledge in this sense can identify valued practices that may be put at risk by releasing a technology, but is not focused on identifying ways in which practices generate risk in relation to the technology.

Chapter 3: Methodological Approach

In order to create a comprehensive risk assessment, it is important to understand how animal biopharming is likely to be implemented if commercial release is approved. A major argument of this thesis is that the risks of animal biopharming can not be considered until an understanding of how the technology is *intended* to be used, and then, how it is *likely* to be used, is obtained. The approach of the thesis rests on the assumption that local knowledge can help identify where actual practice will differ from intended use.

This chapter will give an account of the methodological approach taken here. It will firstly discuss some of the difficulties involved in including local knowledge within risk assessment prior to social implementation. A brief discussion of how this relates to current risk assessment within New Zealand will follow. Lastly, it will discuss the methods used here to identify and elicit useful local knowledge.

Difficulties in eliciting local knowledge before the event

Methods based upon the assumption of perfect compliance with ideal safety standards are inadequate for assessing the risk of biopharming for two reasons. First, best practice may not be practically viable for those involved in the processes of animal biopharming, and, second, some implications of animal biopharming may not be considered within the context of best practice. The risks of animal biopharming can be minimised only if the parameters of its ‘safe’ use are realistic in practice. Therefore, when the intention of developers is stated clearly, or can otherwise be extrapolated, the involvement of local expertise to identify risks and social implications can begin.

A statement by a member of the community in a study conducted for the Ministry of Research and Science Technology reiterates this point, but also points to the difficulties of achieving a clear understanding of a technology’s use:

“We now have an understanding of what they [CRI] want to do or how they are going to use it [GM] or the other reasons for its use. They don’t know— there is uncertainty about the final use. We have to really look at these issues, to take the time.” #827 community (Cronin & Jackson 2004, p.26)

The increasing number of studies on involving the public in assessing technologies and the general increase in rhetoric calling for public involvement has been documented in the previous chapter. Even beyond the recognition of normative reasons for involvement of the public, many governmental reports and studies now recognise the concept of lay or local knowledge (e.g., Cronin & Jackson 2004; House of Lords Select Committee 2000) and perhaps the possibility of useable information arising from public dialogue. That is, they recognise what might be called ‘cognitive’ reasons for public involvement.

However, given the early stage of animal biopharming technology within New Zealand, there are difficulties involved in operationalising the concept of local knowledge in relation to risk assessment of animal biopharming. This is precisely for the reason identified by the participant quoted earlier: how do we know what risks and social problems may arise, when developers themselves are unsure, or unclear, how the technology will be used? The question points to a larger problem for the democratisation of technology decision-making. How can the public be involved practically in risk assessment before a technology is released into society, particularly when its development is in its infancy?

Normative assessments

This question poses problems for both normative evaluations by the public, as suggested by Frewer et.al (1997), and for the practical assessment of social implications. Frewer et al. argue that the public’s acceptance of a technology will not be based on its overall opinion of the general technology, but on the specific processes the technology requires. In the case of animal biopharming, although people have opinions about the technology in general, the benefits and risks of a specific application of animal biopharming, for example the transgenic production of human lactoferrin through cattle, will not be assessed by the public purely from this general opinion. The specific processes involved in producing human lactoferrin in cattle must be assessed as to whether they align with the public’s values. As Frewer illustrates, studies show that the public is not only interested in the ethics of the end product, but also the ethics of the processes involved in creating that product.

The reaction of the majority of lay members participating in a consensus conference in the Netherlands, on the topic of the genetic modification of animals, also illustrates this point.

The majority was surprised about how the genetic modification of animals developed. They found that experts insufficiently made clear what to expect in the future; the goal of genetically modifying animals was not clear enough. (Aarts 1999)

It is not surprising then that most of these lay member participants argued that genetic modification of animals should cease in the Netherlands. Anxiety and legitimate concerns over the intent of those developing the technology and the processes of its development cannot be addressed until it is understood what those intentions and processes are¹¹.

Within New Zealand the public discussion is typically more general than a discussion of animal biopharming; the debate concerns genetic modification overall and often simply “biotechnology”. As Simon Terry has argued, processes of genetic modification are often placed within the basket of “biotechnology is progress”. The government supports biotechnology in general, implying, “Take the entire package or else science in this country will be imperilled...” (Terry 2003). This approach is translated to the public debate, where it is rare that specific processes are discussed.

General participation in risk assessment

The generality of public discussion is extended to the regulatory and risk assessment arenas in New Zealand. Risk assessment in New Zealand is performed by the Environmental Risk Management Authority.¹² ERMA provides few avenues for discussion of specific processes of implementation. The exceptions are public

¹¹ It is easy to fall into a ‘deficit model’ of public opinion when arguing this point. That is to say, by educating the public about the real intentions of the producers, public opposition to a technology will dissipate. Merely stating the intent of the producer, and processes of production, will not necessarily overcome the anxiety and concerns of individuals regarding a technology’s development. Whether or not concerns are alleviated depends upon the nature of those intentions and processes. Thus concerns maybe supported (rather than assuaged) by further education.

¹² ERMA was established under the Hazardous Substances and New Organisms (HSNO) Act 1996 and is a Crown entity. “The Authority’s main role is to make decisions on applications to import, develop, or field test new organisms; or to import or manufacture hazardous substances. These applications are made under Part V of the Hazardous Substances and New Organisms Act 1996.” New Zealand. Environmental Risk Management Authority (e)). ERMA also sets controls on the use of new organisms, and is responsible for promoting compliance with the authorities’ decisions. A more detailed exploration of ERMA’s processes will be provided in chapter 4.

submissions at the time an application is assessed and discussions with stakeholders identified by the applicant. The problem with this approach, as will be illustrated here, is that there is a possibility that members outside of the industry may hold valuable local knowledge which can inform whether specific processes are viable, yet may be unaware that their knowledge is relevant to this application, or may simply be unaware of or uninterested in the ERMA process. Instead of a passive approach of allowing individuals holding local knowledge to initiate discussion, a more sensible approach would be to actively seek this knowledge.

ERMA processes are application-specific

Although it is important to involve appropriate members of the public in discussion of the specific processes of a technology, it is also important to examine how implementation of the technology will be carried out within society. Within New Zealand, risk assessment of GMOs is conducted by ERMA through their case-by-case assessments of GMO proposals that are put forward by groups seeking to develop research or commercialise an application. Assessment is based upon the nature of the application. For example, an applicant may choose to apply for permission to conduct a field trial. ERMA will then assess the risks of a field trial to the environment, society, culture and public health through a cost-benefit analysis. When a company seeks to commercialise a technology, the company applies to ERMA for either a conditional release, which entails controls and monitoring, or a full release where the technology has no mandated controls on its use. The risks of the commercialisation of that product are then assessed by ERMA. Risks of each phase (Containment, Field Test, Conditional Release and Full Release) are not analysed until an application is received to move into that phase; for example, assessment of applications for field trials does not consider risks of commercial release, even when the intention of the field trial is to progress toward commercial release. This means that considerable development costs can be incurred for a technological application that is (or should be) destined, for reasons of risk in the context of release and regardless of the outcome of the field trial, to be rejected for commercial release.

There are two further problems with this process; first, the overall risk of a technology may never be assessed, as each stage of assessment is isolated. A useful illustration of

this approach can be seen within a summary of an ERMA decision regarding PPL therapeutics application to field test transgenic sheep.

...submitters called for a major public debate (national and international) or a Commission of Inquiry on the commercial use of gene technology.....before further work is authorised, or at least before transgenic organisms are released from containment (New Zealand. Environmental Risk Management Authority 17 March 1999)

Concerns could not be addressed by ERMA because “the extent to which the Authority can take into account concerns which are general and not specific to a particular application is restricted under the Act (HSNO ACT 1996) (New Zealand. Environmental Risk Management Authority 17 March 1999)”. Thus, the application-specific nature of ERMA’s process limits both public participation and what can be considered.

Secondly, and of particular relevance here, using ERMA’s approach it is very difficult to involve local knowledge in the assessment of that technology until an application has been made for conditional or full release. It is at this stage that a description of how the product or process would be used in its final form is given. Thus, it is difficult to include local knowledge of how a technology will affect or be affected by social practices until the last stage of assessment, that is, assessment of applications for release into the environment. The PPL Therapeutics case suggests some of the possibilities and limitations of ERMA’s submission process in this regard. In that case, Federated Farmers made submissions querying the processes by which excess sheep will be disposed of in the case of the PPL application for field trials, and used local knowledge of cases in Waimorou to suggest that sheep can escape containment and become feral. This information is mentioned in ERMA’s decision documents, however does not seem to have affected ERMA’s decision, as they state that farm animals are highly unlikely to become feral in the case of field trials.

Ways to incorporate Local Knowledge: Scoping proposed uses

However, despite the limits of risk assessment frameworks in New Zealand, there are ways to incorporate local knowledge, even when specific details of how a technology will be used may be hazy. The solution lies within the concept of what is practically useful in risk assessment, and whether predictive assessment can provide useful information on the risks and social implications of a technology.

By scoping out *proposed* uses for a technology through literature and interviews with those involved in developing or promoting a technology, an understanding of how to involve local knowledge can be gained. Although scoping may not provide exact details of how a technology will be used, this thesis suggests it is worthwhile to analyse the potential risk of a technology *based upon what the developers hope for it*¹³. Involving local knowledge in assessments of the risks of a technology, given the potential uses of the technology in its developed form, is practical in the sense that risks can be identified earlier than if assessment is left until a technology is ready to be fully commercialised. In this way, it is possible to reduce the chances that large investments in a project will have to be abandoned when risks are later identified—or that the assessment process will be influenced by prior investment to proceed despite what would otherwise be unacceptably high risks. This is particularly relevant to New Zealand, where development of animal biopharming is currently, and likely in the future to be, conducted through public funding in Crown Research Institutes (CRIs). If applications are rejected at the last stage, public investment in the development of the technology may go to waste. An alternative is to include previous investment in the cost/benefit analysis. However, as noted above, including “sunk costs” is likely to bias the assessment toward greater risk-taking.

Once future implementation scenarios have been identified, the social processes that may affect or be affected by animal biopharming can also be identified. It is then possible to identify areas of local expertise that may inform what the nature of the risks may be, whether these are avoidable, and whether existing regulatory approaches are able to address these risks. The next section will explain and explore the methods used in this thesis in more detail.

Overview of Methodology

¹³ Interestingly, although ERMA does not officially consider potential future benefits in their risk/cost/benefit equations, applicants commonly cite future benefits in their applications. An implication of this is that developers will often project a technology as a solution to a large medical problem. This encourages public support, and has also been criticised as an avenue to avoiding the moratorium on GM applications within New Zealand (now expired) that excluded medical applications (SAFE 2001). Thus, the process is biased in the sense of permitting one form of speculation (speculation about possible benefits of future release) but exclude another (speculation about possible harms of future release). This is discussed further in Chapter four.

The methods used in this thesis build on those developed by Goven, Cram and Gilbert in the context of research on genetic testing (Goven, Cram & Gilbert 2004; Goven 2005). Their approach seeks to identify forms of expertise that can inform the risk assessment of new technologies, including evaluation of the social implications. It begins with the “scoping” of academic literature (techno-scientific and social-scientific) and other material (such as industry reviews, corporate reports and promotional material, as well as government documents) in order to identify potential development trajectories. In this way, social practices relevant to these implementation scenarios can be identified, and, from this, relevant areas of ‘local’ expertise can be derived. This is followed by semi-structured interviews with individuals who have been identified as likely to hold this relevant knowledge (here called ‘local knowledge’).

Scoping the literature

Scoping refers to the practice of researching relevant literature and expertise on the drivers of animal biopharming, and on the recognised problems and risks that animal biopharming might entail. This practice involved a variety of database searches of academic literature including *Jstor*, *Pro Quest* and *Worldwide Political Science Abstracts* and *ISI Web of knowledge*. As the technology of animal biopharming is in an early phase of development, new developments are likely to occur quickly and unpredictably. In this sense, it was important to conduct general searches through internet search engines such as Google, in order to keep up to date with material and releases regarding animal biopharming. Newspaper articles were also explored using the Factiva search engine, in order to gather relevant information on animal biopharming development and opinion, particularly within New Zealand. Government and organisation websites were also explored, including New Zealand Trade and Enterprise (NZTE), AgResearch, MoRST, The Ministry of Agriculture and Forestry (MAF), The Ministry of Health (MoH), and ERMA websites. These were useful to understand how the government plans to promote, develop and regulate animal biopharming. Reputable information websites such as www.checkbiotech.org were also accessed in order to keep abreast of international developments which could in turn inform likely trajectories for the technology in New Zealand.

Particular attention was given to information pertaining to the potential uses of animal biopharming, risks they may involve, and what players are pushing for its development. Thus, press releases from CRIs and government departments were scanned for useful information on the intentions of those seeking to develop animal biopharming. Journal articles pointing to identifiable problems with the technology were also scoped as potential areas in which local knowledge could offer practical information. Attention was also given to similar technologies and problems that have occurred with them, for example problems experienced by the GM crop industry used in the United States held useful information about the impacts and potential problems with the use of animal biopharming of and on social practices.

This general scoping succeeded in identifying a range of relevant information. Some reports gave particularly useful background information on animal biotechnology in general and animal biopharming in particular (e.g., U.S National Research Council Committee on Biological Confinement of Genetically Engineered Organisms 2004; U.S National Research Council Committee on Defining Science-based Concerns Associated with Products of Animal Biotechnology 2002 ; Kues & Niemann 2004; Dyck et al. 2003). Other sources gave indications of the likely future developments of animal biopharming, and who are driving these developments (e.g., MoRST 2005; New Zealand Association of Crown Research Institutes 2000; Edmond 2002; Beckman & Goldberg 2003). Some of the most useful literature on the possible risks and implications (social, economic and legal) of animal biopharming were Wisner (2005); Weaver (2003); Terry et al. (2001) ; Jaffe (2003) and Pollack (2003).

Scoping extended: Interviewing Drivers and Regulators

This traditional research method did glean useful information on the international context of animal biopharming, and some of the intended uses for animal biopharming in New Zealand. However, a large proportion was not specific to the processes of animal biopharming and its likely trajectory within New Zealand. As there is reason to believe that the risks of animal biopharming may be particular to the local environments and social practices the technology interacts with, more information about New Zealand's possible future with animal biopharming was sought through interviews with traditional 'experts' and those involved in the development of animal biopharming in New Zealand.

Five people were identified and then interviewed who are involved in developing general biotechnology policy in New Zealand, developing or advocating specific animal biopharming technology, or regulating and assessing new organisms in New Zealand, interviewed¹⁴. These people were from MoRST, NZTE, AgResearch, and ERMA. The questions in the scoping interviews were aimed at understanding how the experts involved in the advocacy, development or assessment of animal biopharming see the future of the technology in New Zealand, including how it would develop initially and how the technology would work if scaled up to commercial production¹⁵. The purpose of these interviews, as with the scoping methodology in general, was to identify areas in which local expertise may inform us about relevant social practices likely to affect or be affected by animal biopharming. By combining these semi-structured interviews with a review of relevant literature, a picture of possible avenues for the development of animal biopharming could be derived.

The semi-structured interviews were loosely structured around an interview guide of themes and key questions that needed to be covered. Suggested questions which highlighted the themes were included within this guide. However, it was left to the interviewer's own judgement and discretion to decide how and in what order the questions would be asked. This judgement depended upon the answers given.

The interviews began with a briefing in which the subject was informed of the purpose of the interview, relevant background information, and why the subject was chosen to be interviewed. A project description was offered to the subjects prior to the interview. Following the interview a debriefing occurred in which the subject was offered the chance to ask any questions they may have, and in which the interviewer briefly stated the main points that had been gained from the interview.

¹⁴ All participants for this thesis were asked to sign a consent form, in which they were informed of their ethical rights regarding the interview process (see appendix 1). A general project description was also provided (see appendix 2 for local knowledge interviews and appendix 3 for scoping interviews). In the case of telephone interviews, verbal consent was requested, and an information sheet emailed.

¹⁵ As stated, animal biopharming is in a relatively early stage of development and therefore a clear picture of how it will be commercialised was not possible, even through in-depth interviews with developers. However, this thesis contends that the intentions that those developing a product hold for its use at least offer clues to how it may be commercialised in the future.

Eliciting local knowledge through interviews

It was assumed that after conducting scoping interviews and research, forms of local knowledge that may be informative to the risk assessment and identification of social implications could be identified. Initial scoping produced the finding that biopharming in New Zealand was likely to involve herds of dairy cows genetically modified to express pharmaceutical substances in their milk. A fairly obvious extrapolation was that dairy farmers could offer useful knowledge of practices that may be vital to assessing the implications and risks of this type of animal biopharming in New Zealand.

Semi-structured interviews were carried out with seven dairy farmers. The initial process for locating interviewees was conducted through a search of local dairying websites, such as Federated Farmers and Dairy Insight. The contact details of potential interview participants were provided on these websites. The personal network of the researcher was also used to find dairy farmers who may have been able to recommend interview participants. Several farmers were contacted via email, and then by phone, with a request to be involved in the study. Once initial interviews began, a verbal request was made to the participants to provide the names of other possible candidates for interviewing. As locality was considered important to the types of knowledge that would be offered, requests were made to provide people with farming experience from districts other than Canterbury, where initial interviews were conducted. It was possible then to interview a farmer from Waikato (via telephone), and several farmers with experience in farming from Taranaki and Waikato (but now farming in Canterbury).

Most, but not all, dairy farmers had little knowledge of animal biopharming. Because of this, depending on what the farmer already identified they knew, basic background information was offered on biopharming. This included information on the kinds of animal biopharming being explored, the hazards generally recognised to be associated with animal biopharming (such as the potential mixing of biopharm milk with the general milk supply) and the kinds of controls likely to be recommended to mitigate the risk of those hazards occurring (such as double fencing to keep cows contained in their own paddock). This background information was not designed to summarise the risks of biopharming, but rather to help the farmer relate the particular needs of

biopharming to their knowledge of farming practices. That is, it was intended to ‘translate’ the available information on biopharming into a form that would enable farmers to recognise where their knowledge is relevant.

The usefulness of semi-structured interviews

The interviews conducted for this thesis were based on a semi-structured format. Semi-structured interviews are generally accepted as a useful method to extract in-depth knowledge on particular topics from individuals. The qualitative nature of the semi-structured interview contrasts with the positivist approach. The interview technique does not seek to understand general rules of behaviour as they apply to humanity; the qualitative nature of these interviews allows a focus on “understanding the thinking and behaviours of individuals and groups in specific situations” (Arksey & Knight 1999, p.11). As the scoping of literature already allowed for a level of information that was general in nature, more specific information was needed in order to identify and elicit forms of local knowledge for the purpose of risk assessment.

Semi-structured interviews are also important in that they partially allow for the participant to direct the flow of the interview into areas which they see as relevant but which the interviewer had not identified in advance. As one assumption of this thesis is that individuals may hold specific and experiential knowledge of social processes that are relevant to risk assessment, it is important to allow the participant to identify relevant issues that relate to the general themes of the interview guide. In this way, the interviews may highlight issues or behaviours that may have social implications for the assessment of animal biopharming, which had not been anticipated by the interviewer. Semi-structured interviews allow for identification and exploration of relevant knowledge by the participant, whereas a formal interview guide with specified ‘questions’ instead of ‘themes’ may not allow for the participant to expand on issues unrecognised in the questions

Combining the technical, normative and social: Triangulation

This thesis does not suggest either technical/scientific or normative assessments of animal biopharming are unnecessary. There are obvious reasons for technical information to assess the risks of animal biopharming; for example, an understanding about the molecular processes through which genetic traits spread from modified

organisms is not possible without some form of scientific investigation. Also, normative assessments can help us understand the ethical and political risks of a technology. Similarly, research into attitudes may identify those who are likely to use or avoid a technology, which may in turn suggest areas of future disparity and other implications. However, in isolation these investigations do not allow a full risk assessment. For example, in order to understand the likelihood of gene transfer from genetically modified organisms, it is necessary to understand not only molecular processes of its spread, but also how social practices may shape the opportunities for those molecular processes to occur.

Scoping and analysis of literature generally identified scientific and normative accounts of the issues surrounding animal biopharming. Interviews were required for further information on the social processes of animal biopharming. The methodology is in this sense what Webb et al. (1966) described as triangulation. Triangulation is a technical term “whereby two known landmarks or reference points are used to define the position of the third” (Arksey & Knight 1999, p.21). Webb used this term metaphorically and adapted it to social science method (Webb et al. 1966). In the case of this thesis, the scientific and normative research¹⁶ scoped through the literature in the earlier stages can identify social practices about which it may be useful and necessary to obtain local knowledge. Thus two forms of research, normative and scientific, point to another area which should be explored, that is, social research.

Weaknesses of this methodology

Limited Sample Size

Using semi-structured interviews to elicit local knowledge can offer in-depth accounts of how social processes work, and how this might be adapted to the likely regulations and guidelines that animal biopharming requires. At the same time, given the amount of time it takes to conduct and analyse semi-structured interviews, there can be a trade-off between quality of information received and quantity of interviews conducted. Combined with the time constraints of the thesis process, this resulted in a relatively small number of interviews being conducted. However, the argument of the

¹⁶ This is not to suggest that the scientific and normative issues surrounding animal biopharming are clear-cut or “known landmarks”. Given the nature of scientific development and public opinion this is, of course, impossible. Risk assessment should consider possible outcomes, and therefore in its very nature is speculative.

thesis does not hinge on the number of interviews conducted. Rather, what it aims to do is demonstrate that interviews with properly selected informants (whose selection is informed by the scoping process) can provide information that is clearly relevant to evaluating the risks of biopharming in New Zealand. It does not itself constitute a risk assessment, but points to areas that need further investigation and consideration when risks are formally assessed.

Moreover, the methodological approach drawn on here is one that, in general, seeks out qualitative insight rather than quantitative data (for example, on “public opinion”). Identifying social practices that are relevant to risk assessment requires good ‘translational’ (background) material and thoughtful informants, rather than ‘representative’ samples.

Given the limited time available, it was not possible to explore in depth the usefulness of local knowledge for investigating regional variation. It is quite possible that within different provinces the implications of animal biopharming will be different. For example, in the Waikato where farms tend to be located closer together and on hillier terrain, the practices relevant to containment of animals may differ somewhat from those within Canterbury where farms are more spread out. The farming styles and attitudes within each province may also differ.

Limited range of relevant informants

The complexity and interrelatedness of modern society makes it highly unlikely that an abstract scoping exercise can recognise all individuals and groups relevant to this study. Thus, the scoping exercise should not be considered an endpoint in the identification process of relevant areas of knowledge. Given the interrelated nature of social practices, initial interviews with possessors of local knowledge actually served to identify other forms of knowledge and social interactions that may be relevant, for instance, organic farmers, meat workers and milk transporters. Ideally interviews with people in these areas would have been carried out as well, but, again, time limitations prohibited this.

International drivers and knowledges

Given the limitations of money and time, it was obviously not possible to extend the research to include interviews with overseas actors. However, this may be a weakness given that the New Zealand dairy industry is so dependent on international markets, laws and trends, and biopharming in New Zealand will likely occur as a result of investments by, and partnerships with, overseas actors. Hence, ideally, people with knowledge of, for example, investors' expectations regarding biopharm herd ownership arrangements or major markets' food audit systems and expectations would be interviewed.

Eliciting v leading

As the semi-structured interview is designed to elicit knowledge that may remain unrecognised by current risk assessment considerations, it is important that the participant is able to identify and adapt their knowledge to the topic of animal biopharming. One weakness in this approach is that participants may feel unqualified to do this, as they have not been participants in the dialogue over animal biopharming until this point. It is important then to offer background information on why they might have useful knowledge, and to guide them during the interview into a framework in which they can adapt their knowledge into a discussion of a technology they may initially feel they can offer little information on. A challenge is to resist unintentionally imposing answers onto the participant, but instead to let them formulate these answers themselves, whilst also encouraging an adaptation of their knowledge to the theme of the interview. An attempt was made to structure questions in ways that would encourage the participant to draw on and relate their own knowledge, while also facilitating their identification of avenues of implication and risk.

Conclusion

The methodological approach used here seeks to identify useful local knowledge either omitted by existing risk assessment processes or sought only at a point where it is not easily utilised. It seeks to use this local knowledge to identify both specific and general areas of implication and risk. In this sense, a step away from the more general discussion of GM toward a more focussed discussion of specific practices is encouraged, although at an earlier period than is conducted by ERMA currently. The methodology is also more proactive in seeking public knowledge, rather than the

passive approach of public submissions. Whilst this methodology is limited by sample size and scope, it offers a useful tool to begin understanding how local knowledge can contribute more specifically to risk assessment. The next chapter will discuss current risk assessment and regulation within New Zealand, in relation to its ability to include local knowledge and adequately identify social implications and risk.

Chapter 4: Risk assessment and regulation of Animal Biopharming in New Zealand

Introduction

According to an independent review of New Zealand biotechnology, New Zealand has a primary sector ideal for animal biopharming, and the adoption of animal biopharming in New Zealand could yield significant benefits (Beckman & Goldberg 2003). Consequently, one may question why we should even consider not pursuing, or significantly restricting, biopharming in New Zealand. However, there are some *prima facie* reasons for conducting a thorough exploration of the risks of animal biopharming in New Zealand.

It is clear, for example, that pharmaceutical products produced through animal biopharming should be kept out of the general food supply. It seems uncontroversial to point out that people should not inadvertently consume pharmaceuticals that are intended for other people's particular medical conditions. Beyond this, the environmental consequences of horizontal and vertical transfer of GM material to non-GM animals, soil, and plants is not fully known. Therefore, additional dimensions of transfer of genetic material implicated in pharmaceutical-substance production require further investigation. Unintended intermingling of GM and non-GM products in general has the potential to impact negatively upon New Zealand's export markets, while the ProdiGene episode¹⁷ (and common sense) would suggest that unintended contamination with GM biopharm products would be particularly damaging. Finally, as with other types of GM, one could mention the ethical right of consumers and producers to choose to buy and sell non-GM products, including products free from inadvertent GM contamination.

Therefore, in light of these potentially serious issues there is a need for risk assessment to identify and evaluate risks associated with biopharming in New Zealand, including the evaluation of the possibility of maintaining strict separation of biopharm animals from others.

¹⁷ In 2002, it was reported that soybeans in Nebraska were contaminated with grains of corn modified to produce pharmaceuticals. This occurred because the farmer contracted by ProdiGene to grow the experimental corn, replanted soybeans on the plot that was used for the experimental corn the previous year (Scott 2002). Although the contaminated plant did not enter the food chain, ProdiGene was fined three million dollars, (*Biotech Company is Fined \$3 Million* 2002).

It is somewhat encouraging to note that risk assessment of animal biopharming has begun in New Zealand. This risk assessment has been based upon several applications to field test animal biopharming production in New Zealand. The first of these applications was received on September 10, 1998, from PPL Therapeutics (New Zealand) Ltd, who applied for permission to field-test transgenic sheep, in order to produce the biopharmaceutical human alpha-1-antitrypsin (hAAT), in the Waikato region. AgResearch has also submitted two applications. The first, received by ERMA on December 11, 1998, was to field test genetically modified cattle by inserting a human myelin basic protein gene to be expressed in the milk of the cattle. The second, received by ERMA on May 1, 2002, “[t]o develop transgenic cattle that can express functional therapeutic foreign proteins in their milk, and to develop transgenic cattle to study gene function and genetic performance” (New Zealand. Environmental Risk Management Authority 2002 (Amended 18 November 2005), p.1), and was thus much broader and general in scope than the first application. Each of these applications went through ERMA’s decision-making process. All three decisions were approved with conditions set on how the field-test and containment could be managed, including fencing restrictions and guidelines for disposal of animals.

Unfortunately, beyond the risk assessment of these specific applications, there has been no other specific risk assessment of animal biopharming in New Zealand. Thus, one major limitation of risk assessment in New Zealand is that it does not allow for consideration of risks beyond specific applications. Within the risk assessment of specific applications there have been other limitations come to light, including vague guidelines for how ERMA should analyse social impact, and limited room for local knowledge to be included in decision making. The exclusion of local knowledge in the risk assessment process points to two further weaknesses of the risk assessment process: firstly, it does not allow for a full assessment of social risk and risk deriving from social practices on animal biopharming; and secondly, the public are provided with only limited opportunities to participate in or contribute to consideration of the risks of animal biopharming.

This chapter examines risk assessment and risk management processes and structures currently in place within New Zealand, in order to determine if they provide sufficient

information regarding the social and practical implications of animal biopharming. Of particular relevance here is the ability of risk assessment to consider the risk impact of and on social practices. As this thesis suggests, the ability to do this relies partly on the ability to identify and use relevant ‘local knowledge’; thus, this chapter will also explore whether the current system can and does adequately take account of local knowledge. Firstly, a brief discussion of the general structure and processes of risk assessment within New Zealand will be offered. Secondly, the current weaknesses of this structure and process will be discussed, particularly in the light of how it enables evaluation of social impacts and the use of local knowledge.

The General Structure of risk assessment in New Zealand

The HSNO ACT

Any discussion of the regulatory framework for GM in New Zealand must address the Hazardous Substance and New Organisms ACT 1996 (HSNO), as the framework is based upon this legislation. Section 4 of the HSNO Act states the general purpose of the Act:

Protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms (Le Bas 2005, p.2)

Previously, new organisms, a category that includes genetically modified organisms, were controlled through two pieces of legislation, the Animals Act 1967 and the Plants Act 1970. As these Acts did not require any formal review of genetically modified organisms prior to development or release¹⁸, it was clear that a new Act was required to meet the regulatory issues that were being created from rapid developments in the genetic modification field (Environment and Business Group. et al. 2001, p.6). In 1996 the drafting of the HSNO Act and the inclusion of new organisms within this legislation were passed partly to meet these demands¹⁹.

GMOs defined under the ACT

¹⁸ In 1988 the Interim Assessment Group (IAG) was set up by the Minister for the Environment. Private research was required to apply for review by the IAG only on a voluntary basis. Review of government-funded research was mandatory (Pollak 2003).

¹⁹ Rules on new organisms went into effect in 1998, under the HSNO Act (Pollak 2003).

The regulation and management of GMOs are legislated through the Act as a subset of “new organisms” which are defined by the Act (Le Bas 2005, p.80)²⁰. Animal bioreactors, central to animal biopharming and produced through the genetic modification of the animal, are legally considered to be GMOs, and the responsibility for their management and assessment therefore falls under the Act. The Act delegates this responsibility to the Environmental Risk Management Authority (ERMA).

ERMA

The following section will offer a brief overview of ERMA’s responsibilities and procedures.

ERMA was established by the HSNO Act in 1996 as an autonomous Crown Entity. The ‘Authority’ is a quasi-judicial decision-making body and consists of up to eight members, who are appointed by the Minister for the Environment. They are responsible for all decisions regarding the importation, development and release of GMOs in New Zealand (as well as those regarding the importation or manufacture of hazardous substances). Its overall mission is: “Achieve effective prevention or management of risks to the environment, public health and safety associated with importing or manufacturing hazardous substances and introducing new organisms, and their use” (New Zealand. Environmental Risk Management Authority 2001, p.16). It is empowered to accomplish this through a number of activities, including “achiev[ing] cost-efficient and effective decisions on applications under the HSNO Act which take appropriate account of benefits and costs as well as risks, to New Zealand.”²¹

²⁰ The definition of a new organism in the HSNO Act is expansive. It is beyond the scope of this thesis to discuss the definitional details of new organisms under the Act. For those interested, new organism is defined in Section 2A of the Act.

²¹ The other activities are to “promote compliance with the Act and with the Authority's decisions; promote public understanding and knowledge of risks associated with new organisms and hazardous substances and how to prevent or manage them, and enhance the HSNO Act as an effective legislative framework for the prevention or management of HSNO risks.” (New Zealand. Environmental Risk Management Authority 2001,p.16). Interestingly, the activity of promoting “public understanding and knowledge of risks” suggests a one-sided communication of risk and management, from ERMA to the public, but not vice-versa.

The 'Agency' provides operational support for the Authority, and is organised into eight groups: New Organisms; Hazardous Substances; Strategy and Analysis; Public Awareness; Transfer of Substances; Corporate Services; Māori Affairs; and Legal Services. Of relevance here are the New Organisms and Public Awareness groups. The New Organisms group's responsibilities include:

New organisms operations and operational policy including decision-making, compliance and enforcement, reassessments, Standards, links with other N[ew] O[rganisms] jurisdictions and supporting investigations. Scientific and technical expertise aspects on biological and physical of new organisms" (New Zealand. Environmental Risk Management Authority(c)).

The Public Awareness group, which could potentially play a role in elucidating the social dimensions of risk, currently has the following responsibilities:

Public awareness programmes, corporate communications, Website management and the overview of stakeholder relationships (New Zealand. Environmental Risk Management Authority (a)).

ERMA also includes two other bodies: Ngā Kaihautū Tikanga Taiao (NKTT) and the Ethics Advisory Panel. NKTT is an advisory committee of up to eight members, appointed by the Authority. Its responsibilities include advising the Authority on Treaty implications, risk issues of concern to Māori and as they relate to Māori, and consultation with Māori. The Ethics Advisory Panel was established in April 2004. Its role is:

to provide the Authority with expert advice and assistance on applications under the Hazardous Substances and New Organisms (HSNO) Act which raise ethical and cultural issues and to assist in the development of frameworks and guidelines for dealing with such issues (New Zealand. Environmental Risk Management Authority (a)).

While the Authority has overall responsibility for monitoring and enforcing compliance with the Act and Authority decisions, enforcement activities are delegated to the Ministry of Agriculture and Forestry (MAF), as agreed upon through the Memorandum of Understanding between MAF and ERMA (Pollak 2003,p.9)

Finally, the HSNO Act provides that under certain circumstances the Minister for the Environment can ‘call in’ an application from ERMA in order to make the final decision himself/herself. These circumstances include ‘where it is judged ERMA lacks sufficient experience to decide the case’ and where there are seen to be ‘significant economic, environmental, international and health effects’. In 2003, as a response to the recommendations of the Royal Commission on Genetic Modification, the latter was extended to include ‘significant cultural, spiritual and ethical effects’.

ERMA decision-making framework

Part 5 of the Act states that ERMA is required to make decisions regarding applications, “by evaluating risks, costs and benefits, placing conditions on approvals; and making decisions on transitional licences and other approvals (New Zealand. Environmental Risk Management Authority (a)).” The decisions are based on a decision-making framework, that consists of The HSNO Act 1996 (specifically part 5), The *Methodology (Order)* (1998), and supporting material written by ERMA staff.

The HSNO Act 1996 (specifically Part 5):

Part 5 of the Act sets out the requirements for the Assessment of Hazardous Substances and New Organisms, including to name those most relevant here, guidelines for the assessment of new organisms and hazardous substances, types of approvals allowed, and determination of new organisms.

The broad statements of principle, policy and processes set out in the Methodology (Order) (1998) ²²:

This provides a framework for assessment derived from the HSNO Act. ERMA is obligated to consistently apply the *Methodology* when making decisions. The *Methodology* is discussed later in this chapter.

Supporting material by ERMA staff:

Various technical guides have been issued by ERMA staff regarding requirements of the HSNO Act and *Methodology*. These are designed to help

²² Hereafter referred to as the *Methodology*.

both applicants and ERMA staff in reviewing applications, and discuss specific working processes applied when assessing applications. Some examples of this supporting material are *Policy on consultation & interaction : under part V of the Hazardous Substances and New Organisms Act 1996* (New Zealand. Environmental Risk Management Authority. 1999) and *Preparing information on risks, costs and benefits: for applications under the Hazardous Substances and New Organisms Act 1996* (Gough & New Zealand. Environmental Risk Management Authority. 2000).

Decision Making Process

This section will outline ERMA's decision-making process, as derived from the HSNO Act, *the Methodology* and the supporting material.

It is primarily the applicant's responsibility to conduct risk analysis (Gough & New Zealand. Environmental Risk Management Authority. 2000,p.2). ERMA is required to notify the public through a published notice in four major daily newspapers of its consideration of an application regarding new organisms, including brief details of the application, and a reference to ERMA's website for further information on making submissions (New Zealand. Environmental Risk Management Authority. 1999, p.10). ERMA must review these submissions before making a decision on the application. ERMA is then held responsible for decisions based on the risk/costs/benefits analysis ²³(Gough & New Zealand. Environmental Risk Management Authority. 2000, p.1). ERMA defines Risk, Costs and Benefits as follows: “**Risk** means the combination of the magnitude of an adverse effect and the probability of its occurrence” (Gough & New Zealand. Environmental Risk Management Authority. 2000, p.2). “**Cost** means the value of a particular adverse effect expressed in monetary or non-monetary terms” (Gough & New Zealand. Environmental Risk Management Authority. 2000, p.3). “**Benefit** means the value of a particular positive effect expressed in monetary or non-monetary terms” (Gough & New Zealand. Environmental Risk Management Authority. 2000, p.3).

More specifically, the *Methodology* outlines the types of risks and costs to be analyzed when evaluating an application. Section 9 states:

²³ These consider both monetary and non-monetary costs and benefits.

9. When evaluating the information provided by an applicant (including prescribed information and any additional information) so as to achieve the purpose of the Act, the Authority must

- (a) Recognise risks, costs, benefits, and other impacts associated with the substance or organism in an application which relate to the safeguarding of the life-supporting capacity of air, water, soil, and ecosystems, and provide for this principle; and
- (b) Recognise and provide for the principle of maintenance and enhancement of the capacity of people and communities to provide for—
 - (i) Their own economic, social, and cultural wellbeing; and
 - (ii) The reasonably foreseeable needs of future generations; and
- (c) Take into account risks, costs, benefits, and other impacts associated with the substance or organism in an application which relate to—
 - (i) The sustainability of all native and valued introduced flora and fauna; and
 - (ii) The intrinsic value of ecosystems; and
 - (iii) Public health; and
 - (iv) The relationship of Maori and their culture and traditions with their ancestral lands, water, sites, wahi tapu, valued flora and fauna, and other taonga; and
 - (v) The economic and related benefits to be derived from the use of a particular hazardous substance or new organism; and
 - (vi) New Zealand's international obligations

The authority is also allowed to delegate decisions on low-risk GMOs to institutions which have set up Institutional Biological Safety Committees (IBSCs). IBSCs are predominantly located in Crown Research Institutes and universities²⁴. Delegation is applicable when considering “the development and import of genetically modified organisms that meet the low-risk criteria in laboratory and research situations within contained facilities” (New Zealand. Environmental Risk Management Authority (b)).

Guiding Principles

The authority also follows guiding principles, some of which are derived from the HSNO act, and others which have been developed by ERMA staff, about how it

²⁴ The list of IBSCs in New Zealand: The universities of Auckland, Waikato, Dunedin, Lincoln and Massey University. CRIs HortResearch, Landcare Research, AgResearch, Crop & Food Research, and Industrial Research. Private company, Genesis Research and Development.

should consider an application for the release or introduction of a new organism²⁵. All decisions must be consistent with the purpose of the Act, stated in Section 4, which is:

To protect the environment, and the health and safety of people in communities, by preventing or managing the adverse affects of hazardous substances or new organisms. (Le Bas 2005, p.199)

The guiding principles aimed at upholding the purpose of the Act stated above and are intended to provide general standards and goals which ERMA decisions should meet. Regarding social assessment, which is of particular relevance to this thesis, a rather vague principle is generally cited as the basis for analysis of social implications of an application. The decisions must allow for:

The maintenance and enhancement of people and communities to provide for their own economic, social and cultural well-being and for the reasonably foreseeable needs of future generations. Section 5 (b) (Le Bas 2005, p.199)

The guiding principle of caution, derived from Section 7 of the Act is also relevant here:

All persons exercising functions, powers, and duties under this Act...Shall take account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

Methodology of ERMA

As stated, ERMA is required to follow the *Methodology* when making a decision on an application. The process which ERMA must follow when making decisions is set out in the *Methodology* and discussed in detail in the *Annotated Methodology* (1998).

As stated in the *Methodology* , Section 1:

The Authority, or any Committee appointed under clause 43 of the First Schedule of the Act, and responsible for making decisions under Part V of the Act, must consistently apply this methodology when making decisions.

²⁵ A list of the guiding principles throughout the Act is offered at (New Zealand. Environmental Risk Management Authority.(d))

The Methodology does not prescribe a strict decision making formula or a detailed process, but provides a general framework for making decisions. For example the *Methodology* in Section 2(2) outlines ERMA's role in assessing applications.

- (2) In relation to applications and decision-making, the Authority
 - (a) Must inform applicants (as far as practicable) of the provisions of the Act and this methodology and, where relevant, of the need to obtain approvals under other enactments:
 - (b) Must arrange any statutory processes, including the notification of applications and the holding of hearings:
 - (c) Must review and verify information contained in applications and submissions from the public or, where appropriate, engage expert bodies to conduct the review and verification or to provide additional information so that the Authority may be expertly informed for the purposes of decision-making:
 - (d) May facilitate consultation and pre-hearing meetings between applicants and persons who make submissions opposing the application, where these are requested by the applicant and may assist in the early clarification of areas of technical or scientific dispute:
 - (e) Must co-operate with other bodies (for example, government departments, Crown entities, and local bodies), in particular, when a hazardous substance or new organism also requires approvals under other enactments:
 - (f) May assist applicants to decide on the extent of relevant and appropriate information to be included in any application.

As is evident from the above section while ERMA has specific responsibilities under the *Methodology* there is a wide scope for interpretation within an application. For example, the definition of what an 'expert body' consists of is not provided in 2(c). One interview conducted for this thesis suggests ERMA's general interpretation of what constitutes expertise:

Q. How do[es ERMA] identify who are experts, and can it be members of the community who can offer, who are considered experts...

A: No, I'm talking about the process of going to a scientific expert. [ERMA] looks for information in a range of areas. We look at the effects on the natural environment, the ecological effects, when I'm talking about effects I'm talking about risks, costs and benefits, so risks and benefits. (Interview Participant 1.)

However, it may be possible to expand the concept of expertise to include relevant holders of local knowledge, under the guidelines of Section 2 (c) of the *Methodology*.

Weaknesses of the current regulatory regime

This next section will explore the weaknesses of the system of regulation described, particularly in relation to the types of knowledge it includes and excludes.

Application-specific assessment

In exploring the need to recognize local knowledge earlier, Chapter Three briefly highlighted a weakness of the current regulatory system in New Zealand: the limitations of application-specific assessment by ERMA. Essentially ERMA considers the risk, costs and benefits of a particular organism only within the specific context of its application. There are four types of applications that can be made to ERMA in relation to new organisms and specifically GMOs: containment, field testing, conditional release and full release. Analysis of the risks of GMOs and how these risks should be managed is linked to and limited by the level of development proposed in the applications sent to ERMA. For example, the risks of animal biopharming currently have been analysed only in terms of the risks posed by the specific field tests in the application, even if the field test is a prelude to a hoped-for commercial release. This prevents consideration of how further development or commercialization of this organism may impact New Zealand. This may result in the investment of considerable resources in the development of a specific technological application that in fact poses significant (as yet unconsidered) risks at the release stage. This is illustrated in ERMA's response to public submissions²⁶ regarding specific field tests.

In some cases, ERMA has noted that many submissions in relation to specific field test applications relate to wider concerns about the use of GM technology. The following example from ERMA's decision summary of PPL's therapeutics application illustrates this:

All of these submitters called for a major public debate (national and international) or a Commission of Inquiry *on the commercial use of gene technology, especially that involving gene transfer between species*, before further research work is authorized, or at least before transgenic organisms are released from containment....

...However, the extent to which the Authority can take into account concerns which are general and *not specific to a particular application is restricted under the Act*, and these must in any

²⁶ The process of public submissions will be discussed later in this chapter.

event be weighed on a case by case basis against the benefits of the application. (New Zealand. Environmental Risk Management Authority. 17 March 1999) (Emphasis added)

Although a large proportion of submissions in this particular case were concerned about the future use and wider implications of commercial GM, the example illustrates the limitations that the HSNO Act places on ERMA that prohibit them from considering risks involved in the commercialization of animal biopharming, beyond those directly posed by the specific application at hand. Hence, potential future risks are not included, while public knowledge is also excluded.

Bias toward scientific and medical “future framing”

Interestingly, it is not only the public who are interested in discussing the future implications of developing a technology beyond its specific application. Often applicants seeking approval for field trials will offer future commercial applications as a benefit that should enter into the cost/benefit equation. An ERMA decision on an application to field test GE onions illustrates this point:

The Committee notes that this list [of benefits] is somewhat narrower than the list of benefits originally cited in the application which included potential long-term benefits that may result from the application of the technology currently under development (e.g. projected savings on herbicide costs for growers and reductions in overall herbicide usage in the environment). This field trial is only one step in the process from research to commercialisation. While the potential downstream benefits are relevant to an assessment of the value of the development of these genetically modified onions... the Committee considers that the significant benefits that warrant further assessment are those that will accrue directly from this field trial. (New Zealand. Environmental Risk Management Authority 2003 (Amended 2005))

A vital part of risk assessment is ignored by the approach of ERMA because the commercial benefits of developing a product must be considered in relation to an application. By limiting the analysis to the field trial of the crop, this approach fails to address the fact that the technology's main purpose for being developed is commercial release. This is something that developers will clearly admit and it seems irrational to omit consideration of risks correlating with the intended end use of a product.

One reason for limiting assessment to the specifics of the application is that it avoids future developments rendering past risk considerations redundant. For example, scientific developments could mean that the risks of commercialization can change rapidly. In this way, it may be important to avoid speculation on future risks. However, it is interesting that ERMA does seem to base some decisions on speculation on possible benefits of stages of development beyond the current application. An example from ERMA's decision on PPL sheep illustrates this point:

...the Authority notes that should clinical efficacy be proven, there is a potential for the enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing as a result of health benefits to sufferers of cystic fibrosis (and also potentially sufferers of congenital deficiency of AAT). (New Zealand. Environmental Risk Management Authority. 17 March 1999)

In order to reach members of the community, the medical benefits of PPL's technology would have to be based on some applications beyond its field trial. Even if the field trial produced medical advances these would have to go through further assessment by drug-approval authorities and be commercially produced and distributed in order to allow people to "provide for their own economic, social, and cultural wellbeing" as the decision states. However, the potential medical benefits of the potential future development of this GMO were considered in the field test application. By allowing consideration of benefits, but not risks, of further development beyond the field trial, the process seems to be biased towards applicants and their development of GMOs.

This apparent bias has been noted in public debate. A press release by SAFE (Save Animals From Exploitation) regarding AgResearch's application to test GE cattle voiced concerns about the tendency for applicants to promise large medical benefits in order to better their public relations, and make the application process easier²⁷, a tendency which they referred to as 'medical fraud' (SAFE 2001). The term 'medical fraud' maybe exaggerated, as it is possible that the speculative medical benefits may eventually be realized²⁸. However, SAFE points to the limitations of the process

²⁷ One reason for this approach may be that the moratorium on GM in New Zealand between 2001 and 2003 gave exception for field tests of products that could produce medical benefits. AgResearch had been criticised for applying for tests of commercial agricultural products through the guise of medical research (SAFE 2001).

²⁸ This was not the case for PPL Therapeutics as testing was halted before any benefits occurred. The funding partner Bayer Biological products pulled out of the deal because it no longer saw any economic potential for the trial.

which encourages medical and scientific speculation, but discourages any consideration of social problems and processes beyond that which the field trial itself brings.

Valiverronen (2004) argues that reference to the future is used as a device to frame scientific developments and shape perceptions of developing technology. Valiverronen argues this in relation to the role of the media in constructing the concept of ‘medicine cows’ as a representation of work done on transgenic cattle in Finland. Within this discussion lies the central argument that the representation of the future is a major tool towards power in ‘risk society’²⁹ (Valiverronen 2004), where the future no longer “flows seamlessly from the present” (Valiverronen 2004, p. 366) . Theoretically, if risk assessment allows for one form of future projection, the consideration of future scientific advance through field trials, but ignores another, the possible risks (both social and biological) of commercializing and releasing a technology in the future, then power is skewed to those seeking to advance their application.

It is possible to suggest that risks associated with commercial production will be considered when a commercial application is made, and therefore no product will be commercialized without adequate consideration. However, it is clear that people may be ready and eager to offer useful information on the risks of commercializing or widely releasing a technology before this point. Therefore, in order to adequately account for the risks of animal biopharming, and particularly the social impact both of and on the risk of animal biopharming, it may be important to allow consideration of risks of later stages of development of the organism, earlier.

Application-specific assessment leads to exclusion of local knowledge.

As of yet there is little room for local knowledge to be included in practical considerations of an organism’s risk for New Zealand. The quote from the PPL decision summary used earlier illustrates how the conception of the public as value-

²⁹ The reference to ‘risk society’ refers to Beck’s (1992) theory regarding the increasing complexity of decision-making, and the resulting politicised and competitive arena of expertise. The public must choose the ‘experts’ they trust, from the differing accounts of expert opinion. Hence, the public has lost faith in ‘expertise’ because of the level of contradictory opinions amongst ‘experts’.

holders, together with the limitations of application-specific assessment, may exclude local knowledge which can identify important social risks.

All of these submitters called for a major public debate (national and international) or a Commission of Inquiry *on the commercial use of gene technology, especially that involving gene transfer between species*, before further research work is authorized, or at least before transgenic organisms are released from containment.

Overall the Authority accepted that on one ground or another there were varying degrees of unease within society expressed towards the application, and that to approve the application could conflict *with the firmly held beliefs of some people*. (New Zealand. Environmental Risk Management Authority. 17 March 1999) (Emphasis added).

Although some public submissions called for public debates on supposedly technical issues of gene transfer, ERMA interprets these concerns generally within the category of “firmly held beliefs”. This language at least rhetorically places these public submissions in the category of non-technical and value-laden, hence immeasurable in the context of cost/benefit analysis considerations.

This approach ignores the practical concerns the public may have about the general processes and subsequent risks of the commercialization of GM, an area where local knowledge can offer useful information and where scientific uncertainty remains. Busch et al. (2004, p.26) point to the interesting correlation, found in the 2003 UK GM Science Review, between the areas of scientific uncertainty regarding GM and the public concerns over the uncertainties regarding environmental and health consequences of GM. The correlation between what the public is concerned about and what the science sector is unsure about illustrate that public consultation should not be automatically considered the antithesis to scientific assessment.

The ambiguity and adaptability of rule-following

Several field tests of animal biopharming have been assessed by ERMA and have been approved. This approval, in itself, should not be considered an adequate indication of the safety of animal biopharming in New Zealand. As field tests are largely isolated and contained, and it is under these conditions that the safety of the technology has been considered, the assessment approach falls into what Wynne has described as a ‘black box’ concept (Wynne 1988, p. 149). As Wynne (1988) suggests, “The policy field has been dominated by ‘black box’ concepts which treat technology as autonomous and ‘internally’ unproblematic, or at best, the non-social domain of

technical experts” (p. 149). As the animal biopharming is yet to be released into society and it has not been analyzed in its social context, the risks analyzed regarding field trials relate to animal biopharming as ‘autonomous’ and self contained. This ignores the intrinsic relationships and social worlds animal biopharming will enter, which further production of animal biopharming will entail. Little or no consideration is given to how animal biopharming will be produced commercially, who will be involved, how accidents resulting from human behavior can be avoided, or even whether they can be avoided at all.

It is already evident from other cases that human error is a real risk to the containment of technologies, and specifically to animal biopharming. This is applicable to field trials, but may be even more vital for commercial release in which more parties are involved. For example, there is already a documented case of experimental transgenic pigs being released for food consumption in America. The University of Illinois released to livestock dealers 356 pigs which were part of their transgenic experiments. The university argued that the pigs did not contain the genes of their parent stock; however investigations by the FDA found that records were inadequately kept and they were unable to verify this (*FDA INVESTIGATES IMPROPER DISPOSAL OF BIOENGINEERED PIGS* 2003).

This illustrates Wynne’s assertion that the technology itself cannot be the only factor of assessment when considering the desirability of a technology; it is the human interaction involved with the technology, and how rules and regulations are made and followed, that should be considered (Wynne 1988, p. 149). The assumption that the risks of a technology can be fully contained through rules and regulations ignores the essentially *ad hoc* and ambiguous nature of rules and rule-following that social conditions help create and accidents often illustrate (Wynne 1988, p.149). The university of Illinois example illustrates this well; confusion over how controls should be applied (whether they apply to pigs that did not retain the gene) and how records should be kept (should they indicate which pigs retained the gene, or whether this is possible) led to an undesirable outcome of release of pigs into the food market. These are not essentially technical problems, but relate to the social environment. They relate to how rules are adapted to the local situations they are in.

The literature on local knowledge, as discussed previously in Chapter Two, has noted the flexibility and adaptable nature of local knowledge, and this is important in the case of risk assessment. Adaptation of rule-following may also lead to interpretations of rules not intended by risk managers. This can lead to a greater risk of the technology not being contained in ways that minimise risk. In the context of animal biopharming there will be specific areas in which farming practices, transportation practices, and record keeping will adapt to the controls placed on animal biopharming. These factors need to be considered earlier in the risk assessment process.

The intersection of local knowledge and knowledge held by risk assessors and ERMA staff may end in conflict reminiscent of cases such as Wynne's study of Cumbrian sheep farmers (Wynne 1996), if assessors do not take local knowledge as a legitimate form of expertise. In Wynne's study, the formalised and systematic approaches of scientists addressing the problem of soil contamination conflicted with the knowledge farmers held, which was generally adaptable and less formalised. Farmers, who accepted changing environments, conflicted with scientists who attempted to standardize the farming environment to their own scientific knowledge. Farmers lost confidence and trust in scientists when their local knowledge was ignored because it did not fit the standardised parameters of scientific knowledge; ignoring this knowledge resulted in scientists predicting early resolution of the problem, which they then could not deliver. This suggests further reasons for assessors to recognise farmer knowledge, relevant to animal biopharming, even though this knowledge might not fit the traditional framework of 'scientific' knowledge. In doing so, an understanding of the practicalities of controls and other risk factors maybe garnered, and conflict avoided.

MAF and the difficulties with enforcing ERMA's decisions

In light of these issues around rule-following, it is particularly important that the enforcement of ERMA's decisions and controls be consistent and relatively unambiguous, in order to avoid problems arising through human error. However, several reports have highlighted the difficulties MAF and ERMA have had in coordinating enforcement of decisions (Pollak 2003, p.65). One independent report on the effectiveness of ERMA in relation to the management of new organisms suggests that ERMA and MAF have different priorities that affect the way they approach the

enforcement of rules (Nakhies, Loutit & Rogne 2003, p.9). The institutional makeup of each organization means that each prioritizes different characteristics of controls. The report suggests that whilst ERMA is primarily concerned with risk aversion, MAF is highly interested in the importance of cost-effectiveness (Nakhies, Loutit & Rogne 2003, p.50). In this way, difficulties around rule-setting and rule-following are heightened by the organizational makeup of risk management in New Zealand. This could have the potential to confuse those seeking to follow rules, and undermine both regulatory agencies, which could lead to further opportunity for human error.

Identification of risks and stakeholders by applicants

It could be argued that the social dimensions of risk are covered in the requirement of the ERMA application process for stakeholders to be involved in decision making. As stakeholders can include members of the public, it could be argued that the public is offered a useful avenue to discuss social issues within this process. Under Part V of the HSNO Act, ERMA is required to consult stakeholders on applications to release new organisms. In the words of ERMA,

By gathering information, expertise and comment from a range of stakeholders, a decision-maker will have a better picture of the issues. Consultation can improve the quality of information on which a decision is based (New Zealand. Environmental Risk Management Authority 17 March 1999, p.5)

However, further inspection of ERMA's processes point to the fact that it is primarily the applicant's job to identify and consult stakeholders, as well as to identify and assess risks. ERMA reviews the application and finds areas that need further scrutiny, or areas that need outside sources of expertise. This expertise is viewed in the sense of traditional scientific and technical expertise. Before this review however, it is the applicant who does the majority of assessment and consultation. This process involves the public in a limited way, and essentially assumes that those applying already know the scope of what and who will be affected by their technology.

As there is no formal methodology for how applicants should identify whom to consult, applicants may not know how to adequately identify those with genuinely useful practical knowledge on the social practices that may exacerbate the risk of a technology. Thus, although it is useful to identify stakeholders, individuals and

communities who might have useful knowledge, there is no guarantee under this process that they will be identified. Local knowledge, which can provide useful information on the social impact of animal biopharming can easily be ignored under this arrangement. It is generally considered that neighbouring farmers and local communities should be consulted, but the nature of this consultation, including the kinds of information sought, is left unclear.

ERMA's consultation with the public and evaluation of risk

ERMA may also consult the public as a stakeholder, through the invitation of public submissions. The boxing of the public into the category of stakeholder ignores that within the public different kinds of knowledge combined with different degrees and types of interest exist. This essentially allows those already interested in the process of the application to be involved, but excludes those who may not realize they have useful knowledge to offer, or may not be skilled in the art of formal submissions.

Furthermore, given the nature of social interaction and rule following, local knowledge relevant to the social impact of a technology may arise from relatively obscure areas; it is precisely for this reason that it must be actively identified. The avenue of public submissions is necessary and useful, but should not be considered adequate for identifying all knowledge necessary for the consideration of an application.

ERMA's qualification for considering social implications

Aside from ERMA's limitations in identifying local knowledge, it is necessary to query whether ERMA is qualified to consider social implications. Beyond considerations of Māori rights under the Treaty of Waitangi, there is little guidance for how the social implications for New Zealanders are to be considered by ERMA in their decision-making. The main part of the HSNO Act that can be interpreted as requiring that social implications be considered states that decisions must ensure "the maintenance and enhancement of people and communities to provide for their own economic, social and cultural well-being and for the reasonably foreseeable needs of future generations". However, guidelines for achieving this goal are vague, and it is unclear whether ERMA is expected to have the expertise, or is even empowered to

make such an assessment. There appear to be doubts within ERMA as to whether they are legally entitled to consider social and economic issues:

[W]e have interpreted the requirements of the act to mean that we are able to address social and community effects, and sometimes the lawyers tell us that by actually considering those effects we are on the edge of being *ultra vires*. Because the act, it's quite specific about Maori and also the Treaty of Waitangi. But it's quite oblique about people, it talks about people in communities' ability to provide for themselves, and also talks a little bit about future generations. But it's not very specific... we and the applicants are not very good at identifying effects on society and community. (Interview Participant 1.)

Currently the identification and consideration of social, cultural and economic effects are carried out mainly within ERMA itself. This division between what can be done in-house and what requires 'expertise' again points to the lack of recognition of local knowledge that can benefit practical considerations of risk. 'Expertise' is consulted on areas considered scientific, such as environmental and health effects; the consultation of 'expertise' is not extended to the consideration of social and economic effects. Thus, the practical steps of how a technology will be used within its eventual social environment, and how this social environment will affect the risks of the technology, is considered to be adequately addressed from the abstract view of those within ERMA. This can lead to risks and implications going unaccounted for.

Again, the case of PPL Therapeutics' sheep field trial illustrates this. The evaluation of the economic implications of this field trial was done by ERMA staff; however, they failed to account for the possibility of commercial partner Bayer Biological Products pulling funding from the project. The subsequent problems of how to deal with the GM sheep (whether they could be sold or should be destroyed) and what should be done with the land on which the field trial was being conducted (how long should it be monitored, whether it can be resold) were not considered. As in many cases where problems occur which were not anticipated, these issues were decided in court ³⁰(Andrew 2004; *Court Told Decision on GE Trial Site A Concern For New Landowner* 2004).

This was a social cost that could have potentially been avoided if ERMA had consulted others on the economic implications of the PPL project and looked beyond

³⁰ Bleakley vs the Environmental Risk Management Authority

the applicant's own risk assessment process. It was unlikely that the applicant company would suggest the possibility of economic failure. Therefore, it is implicitly accepted that economic issues will not really be a problem in field trials; however, expertise outside that of the applicant and ERMA could have at least questioned this assumption. Relevant independent knowledge on the workings of the biotechnology industry could have perhaps pointed to the fact that this was a possible risk that needed to be accounted for. This is not a scientific or purely technical issue, but a social and economic one, which could have surfaced with the use of appropriate expertise.

Public Participation outside of ERMA

Bioethics Council

The Royal Commission on Genetic Modification was conducted in 2000, partly in response to the unexpected amount of public interest in applications made to ERMA regarding GM. Applications under the new organisms section of the HSNO act to ERMA would regularly receive large numbers of public submissions. Interestingly, Bas Walker, in the forward to *A Practical Guide to the Hazardous Substances and New Organisms Act*, suggests the new organisms section of the Act was “almost an afterthought” (Le Bas 2005, p.ix). Thus, later surprise at the level of public attention given to applications of new organisms, specifically GM, and the workings of ERMA were seemingly inevitable given this approach. Nonetheless, given the level of interest, it was decided that an overall review of the regulation of genetic modification should be conducted.

After its review, the Royal Commission published a report making several recommendations on how the debate and assessment surrounding GM should be conducted in New Zealand. Several of these suggestions were taken up by the government³¹. One of these was to set up the Bioethics Council, with the purpose of

³¹ There were several notable differences between government decisions and Royal Commission recommendation. The government decided to have a moratorium for two years, which aimed to allow time for more research to be conducted on areas such as gene transfer and socio economical consequences, whereas the Royal Commission only suggested that work on GM should proceed cautiously. When the Royal Commission recommended additional research on gene transfer, etc., it would seem a reasonable reading of their recommendation that the intention was that future decisions be guided by the results of the research; but the government decided to interpret this as simply commissioning the research, not waiting for the actual findings. Another key difference was the Royal Commission recommendation that GM research should, wherever possible, not include animals that are

allowing an avenue for the New Zealand public's ethical, spiritual and cultural concerns and issues to be discussed and considered. It is generally considered that the Bioethics Council offers an avenue for public involvement in GM decisions. The Bioethics Council is designed as a Ministerial Advisory Committee and reports to the government through the Minister for the Environment (The Bioethics Council (a)). Its recommendations are not binding. Interestingly, the RCGM report initially called for the Bioethics Council to include social issues within their range of considerations; however this was not carried through.

A key role of the Bioethics Council is to provide a forum for the public to express its views and values on GM. Whilst it is undoubtedly important to provide a forum for values to be considered, it is interesting that the Bioethics Council only has authority as an advisory panel whilst having no authority on decision making. ERMA reportedly finds it has little use for the Bioethics Council's work. A large part of this may be that the very nature of ethics and values are unquantifiable, and therefore cannot be entered into the risk/cost/benefit analysis.

....what we need in terms of ethical info is threefold, we need some kind of framework for looking at ethical consideration, we need expert advice from ethicists, in areas that are really tricky, embryonic stem cell stuff coming up, and then there's general advice on issues, ethical issues. So the Bioethics Council, they write papers on the general ethical issues, xenotransplantation, but it's far too generic for us to be able to use it anyway. (Interview Participant 1.)

ERMA has begun to develop a framework for addressing ethical concerns, with the aim of producing a more consistent and transparent process (New Zealand. Environmental Risk Management Authority 2005 (a)). A document for public discussion was issued in 2005 outlining ERMA's proposed framework. Under the framework, the responsibility remains on the applicants to address and assess ethical issues, for instance by identifying and consulting stakeholders who may have ethical concerns at a pre-application level. However, ERMA must provide strong guidance

used as food; the government recognised the intent of this recommendation, that GM animals should not enter the food supply, but did not believe further action was required. The government also denied that there was a legal criterion or need for the Parliamentary Commissioner for Biotechnology recommended by the Royal Commission.

on how this is to be done. They may also consult the Ethics Advisory Panel as to whether further information is required.

Interestingly the documents suggest that wise choices regarding applications need to consider information that “goes beyond what might be considered ‘technical’ or ‘scientific’ (New Zealand. Environmental Risk Management Authority 2005 (a)), meaning ethical dimensions³². It also interesting that within the discussion paper, ERMA acknowledges that ethical values should not be ‘boxed’ into a purely isolated domain, but can influence other factors such as “physical, biological, cultural, community, and other considerations” (New Zealand. Environmental Risk Management Authority 2005 (a), p.5). Thus, as the paper suggests, there are ethical considerations in determining the validity of competing claims regarding physical impacts and deciding the level of caution to exercise in relation to scientific uncertainty. This is a step in the right direction, and suggests that members of the public may be able to contribute to knowledge about practical problems, albeit through participation in discussions of ethics.

However, there remains little room for the public to be involved in practical considerations of risk assessment beyond that of public submissions regarding specific applications or avenues for ethical discussion and participation. Whilst ERMA frames the public as holding legitimate knowledge and perhaps expertise on ethical issues, there is limited recognition of the public as holding expertise outside of this area. This thesis posits that the expertise of the public is not limited to ‘values’ but can be extended to areas of practical implication, such as the practicalities of proposed risk management, and the risks to and of social practices in relation to new organisms or hazardous material.

Conclusion

The risk assessment process in New Zealand currently limits the ability to identify and use local knowledge in assessment, particularly before a technology is commercialized. Identification of risks entailed in the technology is restricted by application-specific assessment, and the limited role for public involvement beyond

³² Ironically, the discussion paper states that the procedural standard of “Scientific and rational methods” be upheld when considering ethical dimensions.

public submissions and the Bioethics Council's non-binding discussions of values. As public submissions require participant initiative, valuable areas of knowledge that can contribute practically to risk assessment may be excluded. It is therefore important to develop systems to extract local knowledge beyond the current passive approach. The methodology of this thesis has attempted to address the lack of utilization of local knowledge in the current approach to risk management assessment in New Zealand. The next chapter will discuss the scoping process by which relevant local knowledge regarding the social implications of animal biopharming is identified.

Chapter 5

Results from Scoping: Where is animal biopharming headed in New Zealand, and who holds useful knowledge?

As discussed in Chapter Three, two sets of interviews were conducted for this thesis. This chapter focuses on findings from the first set, scoping interviews. (The next chapter will present findings from interviews with relevant holders of local knowledge.) The scoping interviews, in combination with relevant literature, make it possible to identify certain drivers that are likely to affect the direction of animal biopharming in New Zealand.

Scoping interviews were conducted with five people, from New Zealand Trade and Enterprise (NZTE), AgResearch, MoRST and ERMA. These organizations are involved in policy, research and regulation surrounding biotechnology, including animal biopharming. The primary goal of these interviews was to attain a better understanding of the most likely trajectories of animal biopharming in New Zealand in order to identify which areas of local knowledge could be of significance.

The chapter will discuss, firstly, what the potential benefits of animal biopharming are reported to be, secondly, why New Zealand may be particularly likely to adopt animal biopharming and, thirdly, what possible factors will affect how the adoption of animal biopharming is likely to look when scaled up to a commercial production. It will then become clear what group of people may hold relevant knowledge deemed useful to the assessment of animal biopharming

Drivers: What are the benefits?

It is important to analyse what the projected benefits of animal biopharming are in order to understand whether and how commercial implementation of the technology might develop in New Zealand.

The need for high-value products

One benefit of animal biopharming is that the higher value of products it is designed to produce fits with the expected need for New Zealand to shift from commodity-

based agriculture to an agricultural sector that produces higher-value products for export. The belief that New Zealand must maintain a competitive edge in international markets is implicit within the argument for this shift. For example, an interviewee from AgResearch suggests:

Already certain countries, for example, Eastern Europe and probably South America, have got lower cost of production than what we've got, so therefore we can't maintain an edge. Also we are a relatively small player in New Zealand, even though Fonterra has a large proportion of traded dairy products, if you look at the proportion of actual world markets including internal, it's miniscule. So we can't continue to be, we are not a low cost commodity player anymore. Therefore we have to get into some aspects of higher value....you can choose to make a completely different product, out of cow's milk, or potentially out of meat by actually putting the gene [in] from another animal, and clearly that all forms part of the tool kit for the future of the pastoral industries in this country.

New Zealand has traditionally relied on efficient production methods to produce large amounts of commodities that are price-competitive on overseas markets. As other countries become more efficient with production methods, it is argued that New Zealand's economic competitiveness decreases. Thus, a new focus on quality rather than quantity is considered important to maintain competitiveness. This argument is also expressed in the literature surrounding biotechnology and animal biopharming in New Zealand. For example, the New Zealand Association of Crown Institutes emphasise this point in a paper released in 2000 (New Zealand Association of Crown Research Institutes. 2000, p.26), while NZTE argues that the Biotechnology Sector Engagement Strategy should partly focus on the development of higher-value products for the primary sector and that the highest revenues for biotechnology will be derived from non-food health applications (New Zealand Trade and Enterprise 2005).

Beneficial to agricultural industry and farming practices

It is clear that a major argument for animal biopharming is that it will benefit the farming industry in New Zealand. However, it is fair to question whether animal biopharming is intended to benefit actual dairy farmers through the production of pharma animals, or "the economy" or "the industry" or "the country" more generally through flow-on effects of foreign investment. This question is important

to understand where animal biopharming is most likely to be used in its commercial capacity.

One interviewee supported the belief that animal biopharming is aimed at farmers, the industry, and the country in general. The main benefits of animal biopharming will reach farmers through a revitalisation of the industry and because of the extraordinary gains in value for farmers who choose to opt into this area of production.

Q: Do you have an idea of who you think is most likely to benefit from this development?

I personally think farmers will. The percentage increase would be massive to farmers and New Zealand... [I]f we are trying to grow this country, grow the economy of the country, you address the largest bits of the economy first, and the largest bits of the New Zealand economy are large animal agriculture. And if you can get a 20 percent increase in value return from agriculture in New Zealand, it's like having a wine industry, a creative industry, Lord of the Rings, every couple of months, just by working on those large bits first. (Interview Participant-NZTE).

The participant from AgResearch supported the idea that the New Zealand farm will be the likely recipient of this technology and its benefits, more specifically through the actual adoption of the technology by farmers. In relation to who will be using the technologies of animal biopharming that AgResearch is developing, he states,

Go back to AgResearch's core vision which is something about getting technologies out on farms. [It] [d]oesn't make a grain of sense to me at all for AgResearch to be hogging any of that business once its got to a point when it's ready to go on to a farm. That's not what we are about. And in this particular place, we are doing this because we see it as a vehicle to introduce technologies into N.Z, or to give N.Z the opportunity to use these technologies. (Interview Participant-AgResearch).

Economic uncertainties

However, other interviewees from the policy side were less confident of the economic benefits of animal biopharming. Although it was recognised that New Zealand holds the natural advantages for the development of animal biopharming

commonly cited in the literature (relative disease-free status, strong pastoral sector³³), less confidence was placed in the actual chance of animal biopharming developing, given the safety and regulation issues it faces. An informant associated with Biotechnology Policy at MoRST argues, in his personal view, this point:

My personal feeling, and this is where it is personal and definitely not government policy. My personal feeling is that biopharming, because of the health and safety and containment issues, is unlikely to take off. Unless there is no way you can produce your molecule by a cell culture then there's no real great economic reason for growing in animals.

Patent enhancing and busting vs. discovery of new drugs

The observation highlights another point often made by those questioning the purpose of developing animal biopharming. The pharmaceutical substances currently associated with developments in animal biopharming are already produced through other means. Is animal biopharming a means to develop and produce medicines that would otherwise not be possible? The answer to this is not yet clear. Elebehri (2005) argues, in relation to biopharm crops, that this may turn out to be the case. This point may need to be considered when weighing risks and benefits.

The issue is also highlighted by a comment made by another interviewee identifying the advantages of animal biopharming.

(U)sing animals to produce pharmaceutical proteins allows patent-busting or patent-enhancing on behalf of big pharma.... there's something like, I haven't seen the most recent figure, but tens of billions of dollars worth of IP [Intellectual Property] coming off patent in the pharmaceutical area in the next couple of years. And what, if you are a big pharma company and you have many many millions of dollars held in your IP, in patents on particular drugs, and also you are making a lot of money by selling those types of drugs because of your patent, the last thing you really want to do is relinquish that IP position without a fight when the patent life ends. So if you are able to have another way of making your drug that you can patent, then that basically enhances your patent for a longer life. So you now reapply for another patent based on a different [production method]...but on the other hand, and what makes this whole equation very intriguing, is that you have pharmaceutical companies looking to bust patents. And if they can get around a known patent by using a different method of production, then there [are]

³³ These will be discussed in more detail later in this chapter.

significant gains in being able to do the same product as someone else, but without breaking a patent. (Interview Participant-NZTE)

This informant sees the ability to find new ways of production, and hence new ways of busting or extending patents, as a reason for companies to invest in animal biopharming. Likewise MoRST suggests that pharmaceutical companies will focus on more novel ways of producing purer drugs that are harder to copy (MoRST 2005, p.90). Whilst this may be of benefit economically to pharmaceutical companies, this reasoning partially conflicts with those arguing the possibilities of unique medical benefits developing from animal biopharming found in other literature scoped. If one of the economic drivers of animal biopharming is patent-enhancing or patent-busting, those developing animal biopharming may see no economic value in developing new drugs. In light of this, it is important to point out that animal biopharming may not lead automatically to new medical benefits or technologies³⁴.

Cheaper and larger-scale production

Another advantage of animal biopharming suggested in the literature is that it allows a cheaper and larger-scale production of medicine than conventional methods, which are currently both expensive and time-consuming processes. An independent report on the potential for biotech in New Zealand suggests that animal biopharming is advantageous because it does not require complex monitoring and investment in plant equipment that other processes require (Beckman & Goldberg 2003). Therefore, it is possible to produce larger amounts at a cheaper rate. A paper put out by MoRST cites that this production could cost 1/1000 of what it currently does to produce specialist drugs (MoRST 2005, p.68) Similarly, Kues and Niemann (2004) suggest that conventional production of rare human therapeutic proteins is expensive, time-consuming and inefficient (Kues & Niemann 2004, p.287) and that the use of animals to produce proteins can alleviate these problems.

³⁴ In 2005 AgResearch signed a deal with the drug company Pharma to produce recombinant human lactoferrin in cows. Interestingly, this drug is already manufactured by Texas-based firm Agennix through microbial fermentation processes (Wisner 2005). The company claims its conventional method of production has relatively the same costs as producing human lactoferrin through a method developed by Ventria Bioscience, which biopharms rice to produce a human gene that triggers the production of human lactoferrin (Wisner 2005).

However, one could question whether animal biopharming is feasible or desirable without similarly extensive and expensive monitoring of the processes and conditions of production. Not only must the purity of the pharmaceutical substance be ensured, but also the surrounding environment and the food supply must be protected from inadvertent introduction of pharmaceutical substances. Will this erode or negate the alleged cost advantage of animal biopharming?

Even if animal biopharming does prove to be cheaper, it should be noted that this may not necessarily translate into large benefits for patients. An article in *Nature Biotechnology* suggests that the complex production processes of biotechnology may mean that cheaper knock-off drugs will be harder to produce, in which case it is possible to question whether the cheaper production methods of animal biopharming will necessarily lead to a greater availability of drugs for patients (Herrera 2004). A distinction arises between the concept of new drug development, the desire for new drug production methods, and the benefits for patients.

Healthcare value

The ability to merge healthcare with New Zealand's agricultural sector may also be one of animal biopharming's most attractive features. The Biotechnology Sector Engagement Strategy states that healthcare biotechnology has the potential to generate the greatest economic gains, particularly as the population ages, the cost of healthcare increases and new technology improves (New Zealand Trade and Enterprise 2005). Supporting this is the Biotechnology Taskforce Recommendation Action No. 9, which aims to reinforce New Zealand's relationship with the pharmaceutical industry. Whilst this does not relate specifically to animal biopharming, the focus is on building partnerships with the health industry as well as developing biotechnology research that has human health applications (New Zealand Government Press Release September 18 2003), within which animal biopharming obviously can be categorised.

Why is New Zealand likely to be affected?

The potential benefits of animal biopharming mean that there is definite interest for New Zealand to invest in encouraging its introduction. However there are also reasons why New Zealand seems a particularly attractive and likely destination for companies

searching for locations to develop the technology. Quoted in *Trademark* magazine, Dr Pickering, chief operating officer of Virolonyx Corporation, a developer of HIV vaccines, reiterates this point,

With its disease-free status, a long history of efficient and innovative farm management practices, as well as top quality biomedical research, New Zealand has huge potential to claim its place as the world's natural home for the development and commercialisation of novel animal and plant derived human therapeutics. (Powell 2001, p.15)

Disease-free status

As stated by Dr Pickering a major reason that New Zealand is considered an attractive place to develop animal biopharming is its disease-free status, in particular its freedom from diseases such as BSE and Foot and Mouth Disease. This point is prominent throughout the literature, and was identified by all interviewees as a reason that animal biopharming is likely to develop in New Zealand:

Q: So is there anything about New Zealand that makes it particularly good place to develop biopharming?

[It is] Disease free. The fact that we don't have BSE, we don't have FMD [foot and mouth disease], would be the two absolute keys. But we can go through anthrax and a whole lot of other ones that that's the huge encouragement for companies to come to New Zealand or for New Zealand to [produce] animal based food and health products. (Interview Participant-AgResearch).

Similarly:

[Our] disease-free status is really the key. Our bio security and isolation have meant that ... we are the only country in the world that has no category-one listed diseases and my feeling is that if you were wanting to get ...an animal biosphere product into the health system people would really ...New Zealand has a key advantage in that area. (Interview Participant- MoRST).

The importance of New Zealand's disease-free status also relates to the likely need to monitor animal health through regulation. Kues and Heiner state that general guidelines of the FDA require close control and monitoring of the animal's health and of the performance of the transgenic animal over several generations (Kues &

Niemann 2004, p.288). They suggest that GM farming should be conducted using animals from disease-free countries to make this process easier.

Strong dairy and research sector

New Zealand's farming sector is also a strong reason that animal biopharming is likely to develop in New Zealand. New Zealand has had strong backing both privately and by government for basic research on cattle which may be helpful for the development of animal biopharming (Beckman & Goldberg 2003, p.10). The expertise in farm management within New Zealand may also encourage foreign companies to invest in production of animal biopharming here, particularly as its success may rely heavily on farm management practices, such as the ability to monitor, control and contain animals.

The obvious focus on biotechnology research from government funding will also encourage overseas investment in the development of animal biopharming capability. For example, Crown Research Institutes such as AgResearch are expected to form partnerships with industry and to commercialise research. The Biotechnology Taskforce, set up under the governments Growth and Innovation Framework, sets this as one of its tasks (New Zealand Government Press Release September 18 2003). The focus on practical commercial applications and the government support for partnerships encourages overseas investment in animal biopharming, illustrated in the recent deal between AgResearch and Pharming (NV).

What will it look like?

Given the potential benefits and projected suitability of New Zealand for animal biopharming there is a good case to suggest the technology is likely to reach our shores at some point. The interviews were also supportive of the fact that if biopharming becomes viable, it will probably occur in New Zealand:

[W]ell my feeling is that it will be a New Zealand animal that does it first. I would be very, I would be quite surprised if it's a non-New Zealand animal that gets the first product on the market, I think, the way things are going. (Interview Participant-MoRST).

Recent developments in the field support this claim. There have already been several cases of field tests, as stated in earlier chapters. Commercial ventures have also been attempted. In 1999 biotech company PPL Therapeutics gained approval from ERMA to field-test a flock of four thousand biopharm sheep. The sheep were made bioreactors by “[i]nserting a human gene into the DNA of sheep to produce the protein alpha-1 antitrypsin in the sheep's milk. This protein is a potential treatment for cystic fibrosis (AgResearch 2000).”³⁵ The operation was cancelled and the flock slaughtered when partner company Bayer Biological Products no longer felt the operation was economically viable. Bayer was originally meant to carry out the clinical trials and marketing of the drug (NZPA 2003).

More recently, AgResearch has signed a deal to produce recombinant human lactoferrin in cow's milk, with a Netherlands-based biotechnology company called Pharming (NV). The purpose of the deal is for AgResearch to develop the capability for market-scale production of the protein, as well as developing purification capabilities within New Zealand. AgResearch believes that at best calves will be in the paddock by mid-spring 2006, under containment. AgResearch has received approval by ERMA to field-test these transgenic cows under a previous decision given in 2002 to conduct a broad development of GM cattle for non-commercial purposes. ERMA however has not given AgResearch approval to develop commercial herds of the transgenic cows as several press releases³⁶ suggest AgResearch planned to do (Atkinson 2005).

The decision by ERMA has come under heavy criticism particularly as the public was not included in any discussion or review of the decision. In making the decision ERMA also amended their previous decision by allowing AgResearch to use imported GM semen developed by other biotech companies. It has been argued that this will open the door for overseas companies to use New Zealand as a developer and producer of GM animals (GE Free NZ 2005).

³⁵ This information was taken from AgResearch's website.

³⁶ For example, a press release by Pharming (NV) on their website states, “AgResearch shall bear costs associated with the initial production of rhLF [recombinant human lactoferrin] and support the commercialization of rhLF through its extensive network in the South Pacific and Asia. (Pharming Group N.V 2005)”.

The recent decision by ERMA strongly suggests that development of animal biopharming for commercial purposes is likely to be attempted at some point in New Zealand. The next section identifies several scenarios for how animal biopharming may develop and be used in a commercial sense. In doing so, it will become apparent what forms of local knowledge may be useful for the assessment of the risks of animal biopharming in New Zealand.

The intentions of those developing animal biopharming

As discussed in Chapter Three, in order to know where the technology is headed, and what areas of local knowledge maybe useful, it is vital to understand how animal biopharming is intended to be used by those driving its development. This next section will briefly highlight how the intentions of those developing and encouraging animal biopharming could affect where it operates, the size of its operations and who will be involved and affected by those operations.

Dairy

There are several types of animal that can be used for animal biopharming within New Zealand. For the purpose of this thesis, a focus has been placed on animal biopharming involving dairy cattle. Through scoping of the literature and interviews it has become apparent that the dairy industry will be particularly impacted by the introduction of animal biopharming. As the infrastructure is already developed here to farm dairy cows efficiently, those developing animal biopharmed products can save money on start-up costs. As one interviewee put it:

[E]very time you make a change in an industry it costs money. Because you've got to train people, you've got to put in new processes and new technologies and structures, so it stands to reason that you make as few changes as possible to keep the costs down. Hence in New Zealand you do meat and milk. (Interview Participant-AgResearch).

This is perhaps why animal biopharming will be more likely to be used on dairy cows than other animals such as pigs, which are also capable of producing human pharmaceuticals, and are considered the most appropriate animal for production of organs for xenotransplantation (into humans).

Well that's what we farm in New Zealand, yeah we've got pig farms, but that's only for domestic consumption. We don't have hi-tech pig farms. We don't have a researched pig industry in this country. The pork industry goes to Australia for its research. Likewise there is no research poultry industry in this country. (Interview Participant- AgResearch).

A report prepared by the MoRST in 2005 predicts that animal biopharming will be active within New Zealand by 2008, to the point that factories of livestock will develop across the country (MoRST 2005). Within the livestock category, this thesis has focused on dairy cows for a variety of reasons. First, as illustrated above, New Zealand has a natural advantage in expertise and experience in dairying, therefore it is natural that companies will wish to use the systems already developed for dairying in the development of animal biopharming. Second, there is a perception that large animals are safer to use in biopharming than crops and easier to contain (Pollak 2003, p.59). As crops can potentially contaminate non-biopharm crops through pollination via insects and wind, animals are considered easier to isolate. Large animals are easier to see also, and therefore detection of escape would be less challenging. However, there is a high level of debate as to what constitutes containment of animals, as will be discussed later in this chapter.

How many cows?

It is generally considered likely that fewer cows will be needed to produce pharmaceuticals than are used in traditional dairy operations. The size of the herd will affect how the animals are raised, and what management system is required. Interviewees indicated how the size of the herd could vary depending on market demand and scientific capability. The participant from AgResearch suggests:

[Y]ou can do sums that will tell you that a herd of 12 cattle can produce a substantial amount of national, or the international requirement. So potentially if everything is optimized you can get some very efficient small herds that are producing large amounts of high value milk. That's a possibility. Another possibility is that you say actually I'm not going to go for intensive system, I'll have more animals that are perhaps a bit less efficient...it will depend on the economics of it. It also depends on the cost of purifying the product out of the milk, assuming that that is what you are going to do.

In another interview with an informant from NZTE, the suggestion that utilizing farmer's experience in farming may mean that larger herds are used:

... I guess you are looking for the economies of scale, and you would be looking to utilize the knowledge that we have in handling 250 cows with one man and a dog, which we do on our dairy farms. So I guess if you are smart you would want to get all the productivity gains that would come from good New Zealand farm practice, but also obviously the significant revenue gains from producing something other than milk.

Higher milk cleanliness

One interviewee illustrated the need for even higher standards of cleanliness for transgenic milk. In order to extract pharmaceuticals from milk it is necessary to have ultra-clean milking facilities.

[I]f you start pulling milk out of a cow that has got a protein expressed in it, you are going to have to really start looking at the hygiene side of it. I mean New Zealand dairy farmers are very clean anyway, but they are going to have to go up to almost lab standards. (Interview Participant- NZTE).

There may need to be new facilities to ensure this status of cleanliness.

Nutraceutical or pharmaceutical

The stringency of regulations may depend on whether the product being produced is a nutraceutical or a pharmaceutical. A nutraceutical is a food or food extract that is thought to convey medicinal or health benefits, but is not considered a drug (if consumed as food, it is known as functional food). Interviews with those supporting the development of animal biopharming indicated that the decision to produce nutraceuticals may come down to market demand:

Q: In terms of the nutraceutical, is that something you are aiming for now perhaps because the regulations are less stringent?

No it's purely a marketing thing. I mean, again I'm not talking about lactoferrin here; I'm talking in general terms it's purely a marketing issue. And whether the market wishes products from this source. (Interview Participant- AgResearch).

Depending on economic factors there is a possibility that nutraceuticals could be produced from biopharm cows. This would bypass more stringent regulation in terms of clinical trials. If this is the case, it can be expected that the commercial production of biopharm cows would occur more quickly than if cows are producing pharmaceuticals.

Who owns the cows?

Finally, the operation of animal biopharming will also be dependent on the management and ownership structure in place. Interviews from the scoping section indicate that it is most likely that animals will be owned by the developer, and managed by farmers. However, other options are possible such as a group of farmers banding together to own an operation, or the operation being subsidised by the pharmaceutical company:

I think it would really depend on the business bottle...what you would get effectively is farm managers farming the animals that are owned by a biotech company or a pharmaceutical company... [b]ut I guess a smaller scale example is farmers that band together and decide to go organic in their area, and then sell together. You know they basically, they started on their own herds, they got the technological information on what they needed to do, they needed to do this and that to become organic milk producers, so they did. Obviously there is a massive difference in investment in time and regulations, but it would be like that. It would be a group of farmers that saw the business case, worked with a provider, worked with a pharmaceutical company and you know something came out the other end of it. (Interview Participant- NZTE).

Possible Controls Related to Risks:

A large part of how animal biopharming will look if scaled up to commercial production will depend on what the risk assessment process deems to be the required controls for its safety. These controls will be determined based on what the perceived risks of animal biopharming happen to be. This is particularly important given the recent amendment to the HSNO act in 2003 to include conditional release as one of its categories of application (New Zealand. Environmental Risk Management Authority November 2003). Previously applicants could only apply for containment, field test or full commercial release. Full commercial release meant that the product required no controlling or monitoring. The inclusion of

conditional release allows a new organism to enter the environment whilst still having controls placed on its use.

It is important to understand what these controls are likely to be for two reasons. Firstly, the controls will affect who will use and own the technology, for example, as compliance with controls may raise the cost of production significantly, controls will determine whether it is economical for farmers to run and own the operation. And secondly, it will affect how the technology is used, for example, what type of production model is required. Scoping likely controls makes it possible to identify holders of local knowledge that may be relevant to assessing the practicality, risks and likely effects of the controls.

Animal biopharming likely to be a conditional release

Several interviewees indicated that they did not expect animal biopharming to be approved as a full commercial release, and therefore controls will be influential in the use of animal biopharming:

Someone could apply for a full release, but I think they'd be better off going for a conditional release. Because the kinds of conditions you put on would be that it could only be done in a set number of properties. It just means that, particularly thinking of cows, if anything did go wrong then you'd be able to retrieve it, put it back. (Interview Participant 1).

The quote suggests that there are already several perceived risks of animal biopharming that may lead to certain types of controls being put in place for commercial operations.

This next section will briefly identify some of the likely controls that will shape how animal biopharming operates.

Keeping milk separated from general food supply

One of the main risks of animal biopharming involving cows is the possibility of GM milk entering the food supply. This could have effects on human health, the market perception of non-GM milk and on the rights of consumers and producers to decide what to purchase or sell.

Depending on the protein or pharmaceutical being produced within the cows' milk, the safety of consumption will differ. Although most pharmaceuticals will have to be extracted from the milk, rather than consumed through milk, it is generally recognised that harmful health effects could result from inadvertently consuming pharmaceutical substances by drinking the milk. The nature of the effect would depend on the substance and on the individual involved. Nutraceuticals are more likely to be intended for consumption in the milk itself; again the risks of inadvertent consumption by the public depend on the type of substance involved and the particular individual consuming it.

Beyond health issues, for the economic well being of both GM and non-GM dairy farmers in New Zealand, it will be vital to separate both types of biopharm milk from non-biopharm milk. GM milk will likely be closely monitored, and high standards of cleanliness will be required in order to extract pharmaceuticals. As it will be worth more than normal milk, the results of mixing the two could be costly. On the other side, the perception of New Zealand non-GM dairy by overseas markets would be affected negatively by an accidental release of GM milk into the food supply.

The incident of the accidental release of Starlink corn into the human food chain, generally considered only a minor health hazard, illustrates the economic cost of accidental leaks of GM substances into the food chain. Starlink was GM corn which was not approved for food consumption, but was detected in human foods in 2000³⁷. The Starlink case cost millions to recall contaminated food, clean plants, and settle lawsuits³⁸. It was also costly to non-GM farmers, as Japan temporarily ceased importing U.S corn in October 27 until they were confident that testing

³⁷ The Starlink gene Cry9C was found in a sample of Taco Bell shells on September 18, 2000 (Schmitz 2005). The gene was detected later in other foods.

³⁸ Schmitz, Schmitz and Moss (2005) illustrate the cost of two such law suits. *Fingers et al. v. Kraft Foods North America, Inc.*, et al. was a case in which plaintiffs claimed they had allergic reactions to contaminated food. Although testing found none of the plaintiffs had antibodies that would indicate an allergic reaction to the Starlink gene, a settlement of \$9 million dollars was approved in 2002 (2005, p. 392). *Mullholland et al. v. Aventis Crop Science USA Holding, Inc.* was a case filed by non-Starlink corn growers who claimed damages from contamination. This involved loss of market value as well as storage and transportation costs resulting from contamination (2005, p.392). The case was settled for \$110 million in 2003.

mechanisms for Starlink were adequate. An article in Agribusiness journal estimates that the Starlink episode resulted in losses between \$26 and \$288 million dollars for producers in the U.S (Schmitz, Schmitz & Moss 2005).

The Starlink episode illustrates the importance of keeping GM material not regulated for the food chain, out of the food chain. In the case of animal biopharming in New Zealand, this will inevitably mean that modified cows' milk should be separated from non-GM cows' milk. Controls will have to be put in place to attempt to ensure this.

Keeping cows separated from the food chain and the use of excess cows

The National Research Council in the United States also identifies the importance of restricting biopharm animals from the food chain. However, issues can arise given the nature of animal biopharming in relation to dairying. As the valuable protein is produced in the cows' milk, and cows lactate in order to feed calves, it is not possible to produce the milk without the birth of new calves. These calves will essentially be worthless if not needed for the herd (e.g., only a small herd is needed [see above] or they are males) and not welcome in the food chain. It may be likely that developers seek approval to use excess cows for some other use such as food (U.S National Research Council Committee on Defining Science-based Concerns Associated with Products of Animal Biotechnology. 2002, p.54).

However, it is possible that regulation will not allow this. Even if a transgenic animal does not contain the product of an introduced gene, and therefore is perhaps unlikely to have human health consequences, the possibility of such a threat and the regulatory problems this would cause, leads the National Research Council to recommend keeping these animals from the food chain (U.S National Research Council Committee on Defining Science-based Concerns Associated with Products of Animal Biotechnology. 2002, p. 54). New Zealand regulators may well do the same. This raises the question of how the calves will be treated and/or disposed of, and what costs that might entail.

Stop animals from escaping and entering

It will also be likely that controls are mandated to stop the intermixing of transgenic and non-transgenic cows. Field tests of transgenic cows in New Zealand have focused on containing the cows, for example by using double fencing which is two metres high in order to stop the animals mixing with neighbouring animals. Identification tags to monitor where cows are at any time are also considered important, both to avoid escape and to ensure that inspectors are able to identify cows easily. The possibility of transgenic/non-transgenic interbreeding could lead to incidents such as Starlink, in which biopharm substances are inadvertently consumed and major economic repercussions occur, or could undermine the viability of the biopharming enterprise by compromising the purity of the biopharm herd and its product. Presumably, controls will (attempt to) address this.

However, it is generally considered easier to contain transgenic cows than transgenic plants, mostly because they are more visible, and less likely to survive undetected in the wild. This could lead regulators to mandate less stringent controls.

Horizontal gene transfer through soil and other material

The possibility of horizontal gene transfer³⁹ is a debated issue within risk assessment of animal biopharming. The National Research Council suggests “Although there is no example yet of acquisition of any gene, including drug resistance markers, by bacterial flora living in a transgenic animal, the spread of introduced genes remains a possibility, albeit remote” (U.S National Research Council Committee on Defining Science-based Concerns Associated with Products of Animal Biotechnology. 2002, p.52). The GM protein contained in the cows’ milk, or the genetic material that “programs” the expression of the protein, may also be contained in blood, secretions, faecal matter and other waste material. This could be of concern, as it could be ingested or spread by other organisms or animals. For example, blood-sucking insects or soil bacteria could become affected by, or vectors for the spread of, the altered genetic material. Whether or not this is recognised as a danger will determine whether any effort is made within the regulations to contain more than the cows themselves and their milk.

³⁹ This is the transfer of genes other than ‘vertically’ (i.e., from parent to offspring).

Another concern is that the effects of proteins in novel environments are largely unpredictable. For example, the BSE virus developed from young calves consuming meat and bone meal (MBM), from which prion proteins were acquired which changed shape and became pathological (*Cambridge scientist reviews origins of BSE* 2001). Some suggest that similar prion diseases could develop through genetic modification of animals (Weaver 2003, p.25). This may happen if the protein is able to be passed and expressed outside of the transgenic cow's milk or from the consumption of a cow's transgenic milk (U.S National Research Council Committee on Defining Science-based Concerns Associated with Products of Animal Biotechnology. 2002, p.52). The National Research Council argues that "[t]ransgenes might be expressed at a low level in various tissues in which the promoter is not expected to be active" (U.S National Research Council Committee on Defining Science-based Concerns Associated with Products of Animal Biotechnology. 2002, p.66). If this is the case there could be an unpredictable spread of genes and proteins. Therefore, controls may be set in place to limit the spread of soil or cow waste matter within or from GM farm to non-GM farms.

Health of the cows and disposal of unused milk and carcasses

As the animals are likely to be worth a large amount of money, their health will be paramount. If an animal becomes sick, it will be unable to be used for pharmaceutical milk. Therefore the disposal of sick animals or the disposal of their milk may also have to be regulated to ensure the material is not spread off the farm, and in turn the potential risks of inadvertent consumption and horizontal gene transfer are limited.

Conclusion: Identifying relevant knowledge

Scoping research made it possible to sketch the parameters of how animal biopharming might develop and who may be affected by animal biopharming in New Zealand. Through the literature and scoping interviews, it became obvious that there is perceived economic incentive to pursue animal biopharming in New Zealand and, given New Zealand's well developed dairy infrastructure and freedom from BSE, it is most likely to develop within dairying. It is also became clear that some form of controls will be needed (and likely mandated) in order to manage the risks of animal biopharming identified in the literature. Such controls will affect

and be affected by the behaviour of those producing animal biopharmed products. It seems logical to assume therefore that dairy farmers are likely to hold useful knowledge on how their current practices may be affected by animal biopharming, whether they can see additional risks in the operation and whether likely controls will be practical or realistic. The interviews with dairy farmers focused on possible scenarios for how animal biopharming might develop, given the information collected from the scoping section, and what the farmers thought could be relevant to the assessment of the risks of these developments.

Chapter 6: Eliciting Local Knowledge: Results from interviews with dairy farmers

In the previous chapter, particular focus was placed on different drivers of animal biopharming, and their potential to shape future applications on a practical and commercial level. This chapter will discuss what has been learned from interviews with dairy farmers about the risks of biopharming in the dairy sector, particularly with regard to practical issues of implementation.

Seven farmers with varying experiences, from Canterbury, Taranaki and Waikato, were identified and interviewed either by phone or in person. These interviews focused on how animal biopharming is likely to be implemented in the dairy sector and how the implementation is likely to be shaped by practices in the sector. The discussion here will first be organised into three categories of risk that emerged from the interviews: rule-following, containment, and economic factors. After exploring these areas in detail, the chapter will apply the findings to several ownership and regulatory scenarios for animal biopharming in New Zealand. This is important, as various implications identified by farmers will be dependent upon which scenarios of management, ownership and controls are in place.

Biopharming risk areas

Findings on the sources of risk arising from farming practice can be categorised into three general areas. These are:

1) Ambiguity of rule-following:

The interviewees noted the risk of relying heavily on controls to ensure the safety of animal biopharming. This is particularly relevant given the complexity of rule-following within the social context of dairy farming. Both practical and general thematic areas of risk are highlighted in this section.

2) Containment factors:

The interviewees identified several areas of practice that may affect the ability to contain animals and soil within an animal biopharming operation. Significant

changes to farming practice may have to occur to ensure animal biopharming containment.

3) Economic Factors:

A large part of the implications of animal biopharming will be determined by economic factors. These factors will affect farmers behaviours as well as the practicalities of controls.

Before beginning, it is important to note that at least some of the risks and implications identified in these interviews are avoidable through careful planning and considerable spending. However, it is assumed that in order to avoid hazards and manage risks, it is generally useful to identify them first, if possible.

Ambiguity of rule following

The literature on local knowledge and risk assessment is littered with examples of individuals not following rules and behaving in unexpected ways (at least to those looking from the outside), generally making risk minimisation more complex than it may initially seem. Rules and controls are often demonstrated to be unrealistic, impractical or irrelevant in the context of actual rule-following and behaviour on a ground level. The Starlink episode and Britain's BSE debacle, among others⁴⁰, point to the need to understand rule-following from within the social dynamics of the rule-following context. Behaviour can be complex and adaptable, thus often resistant to fixed standards and rules. Wynne articulates the point clearly: "Practices do not follow rules; rather, rules follow evolving practices" (Wynne 1988, p.153).

⁴⁰ Irwin's (1995) example of the public dispute between farm workers and British regulatory authorities over the use of the herbicide 2,4,5-T is particularly relevant here. Farm worker's campaigned to have the pesticide banned to the Advisory Committee on Pesticides (ACP). They provided the ACP with a dossier of information on the 'real world' uses of the pesticide and examples of the pesticide being linked to ill health. However, this information was discredited by the ACP because it did not fit the scientific model of proof. The ACP felt the pesticide was safe for use if recommended procedures were followed; however such information was based on flawed assumptions of the social environment the pesticide was to interact with. As Irwin suggests "[t]he argument for a ban on the pesticide was...constructed in terms of an inherently uncontrollable technology and of a messy and heterogeneous 'real world'. The advisory committee's insistence on 'recommended' conditions made little sense within this social and technical model of pesticide administration" (p. 113). In the case of Starlink, faulty assumptions about the planting practices of farmers assumed that the segregation rules for GM corn would be easily followed, which thus provided a false confidence in containability (Taylor and Tick 2000). The BSE example relates to scientific recommendations made to ensure safety of cows that ignored the social realities of meat practices in Britain.

Given that animal biopharming is likely to be, at least initially, subject to strong controls⁴¹, farmers recognised and highlighted the risk in relying heavily on regulation to maintain safety. The following interviews illustrate the importance of looking at how farmers follow rules when seeking to gauge the risk and implications of a control-intensive operation such as animal biopharming. This next section will briefly discuss the interviews in relation to farmers' behavioural and attitudinal approach to controls and rule following.

The effect of ownership on the attitude of farmers

Many of the farmers interviewed suggested that the effectiveness of controls will be affected both by how farmers interpret them and how they feel about them. Most of the interview participants noted that a farmers attitude and commitment to following controls may be influenced by whether they own the animal or not. If animal biopharming is likely to be run under a farm-management operation, seen as a likely scenario in the previous chapter, several participants viewed this as a potential area of risk:

In normal mainstream farming people who are managers are trying to get ahead. People who own the cows will do everything, come hell or high water for those cows, because they are theirs. And... they would take care of the farm better, they would take care of the animals better, they are more specific (sic) with their cows. Share milkers and farm owners... they will bat for a cow until it dies. Whereas a farm manager goes, "I don't own it, what do I care?" It's an attitude. I mean if you got the right farm manager, it could be good. The other thing is if it was a farm management position, you would have to get quite a legal binding document with him saying he can't do what normal practices he thinks he could do.

Q: Such as?

Well if he was only there for a year, he could take something with him to the next farm.... An owner you are in it boots and all, and you are going to make sure that it works. Whereas a manager its like "I'm only here for a year, what do I care?" It can be an attitude thing. (Dairy farmer participant 1)

⁴¹ As stated earlier, this may depend on the classification of what health product the animal is designed to produce. For example, as Pharma (NV) is seeking to classify human lactoferrin as GRAS (Generally Recognised as Safe) through the FDA (Food and Drug Administration, U.S), this may have implications for the level of controls required for that particular product in New Zealand (Cow produced Lactoferrin Completes GRAS notification January 2006).

According to this interview participant, the commitment to following controls may need to be factored into a risk assessment analysis. Such a consideration falls outside the bounds of purely technical evaluation, given the unquantifiable nature of the subject. However, in order to avoid the risk of poor control-following, it may be necessary to evaluate the different affects of ownership on farmer attitudes and rule-following and include this in a risk assessment equation.

Beyond the more general theme of rule-following, the above quote identifies an area of practical risk. Behaviour such as taking property from one farm to another when a job is finished illustrates a practice which will need to be considered when seeking to set appropriate controls for animal biopharming. If not recognised and controlled for, such practices could affect the spread of animal biopharming material, particularly given the level of job turnover among farm employees (discussed later in this chapter).

However, whilst the majority of farmers interviewed agreed that ownership will affect attitude and in turn, may affect willingness to follow rules, one farmer believed farm managers would be particularly capable of performing the proper procedures:

Q: So a farm manager is someone who is hired to work...

To run a farm, is very capable of running a farm. Has got the right skills, and the people skills and the animal husbandry skills , and it probably takes them, they probably have to be farming for up to six or seven years at least before they can be called a competent manager...a farm manager now is a pretty skilled and qualified person. So they should be quite confident of handling what you are suggesting here. (Dairy farmer participant 2).

The differences in opinion between farmers illustrate the diversity within the farming community on attitudes towards risk. This supports the literature that suggests local knowledge is not always unified within a community.

Farmers' perception of risk and rule interpretation

The farmers' own perception of what the risk of an operation is may affect the likelihood that they will accurately follow controls. Perhaps unsurprisingly, if a control is felt to be arbitrary, it may not be followed. In relation to risk assessment, it

calls into question whether it is possible to have confidence that risks are truly minimised by controls, given that their effectiveness is reliant on farmer discretion.

For example, one farmer indicated that there could be potential for rule skipping in relation to escapes of GM animals from containment. The farmer admitted that he would be unlikely to report any escape of GM cows onto his farm because he would not want to deal with red tape and potential monitoring requirements for an issue he did not believe was a risk. Thus, in the case of an animal escaping onto his farm, he would be likely to return it without reporting the case, even if this was required to be done by regulation.

As with the last section, the farmer's comments illustrate a practical point, as well as supporting the general theme that rule-following is flexible within farming culture. Practically, the relationship between neighbouring non-GM farmers and GM farmers may have implications for the ability to contain GM animals or material, particularly if there is limited ability to regulate behaviour after an escape occurs. A potential reluctance of neighbouring farmers to cooperate with controls and monitoring could be a real problem with regard to reporting and monitoring containment problems. This raises the risk of milk or meat from animals that have been in contact with GM cows, or escaped GM cows themselves (or their descendents), entering the food supply.

Similar issues are illustrated by the following farmer's discussion of "slackness" around management of herds containing tuberculosis-infected cows:

Well there are some areas where you can't move animals in and out of, and the rest of it is free. And you just have to record the movement of animals from one farm to another. But that is pretty, well; I would say it is pretty slack. The officials would say that it is not.

Q: how is it slack?

Well it is pretty easy to get around it, let's put it that way.

Q: how do you do it?

Well you just simply do it and don't tell anybody... But I mean that is going to change dramatically in the traceability work that is being done now; with the traceability of animals...it is just a paper-based system at this stage, and an ear-tag system. And ear-tags fall out, whether voluntary or involuntary. I mean we are talking about a very small proportion of farmers that are doing this sort of thing, like minute. But it is happening. (Dairy farmer participant 4).

On a practical level, it is clear from the above quote that an up-to-date technological system for monitoring GM animals will be required. However, the quote also further illustrates the more general theme of rule-following. In the case of animal biopharming, the examples illustrate that an over-reliance on controls to ensure safety was considered a risk by interviewees, given the nature of rule-following within dairy-farming culture.

Employment and human error

Quality of employees, the number of workers employed and the high staff turnover rates were all identified as potential areas of concern for animal biopharming, whether this involves employment by a pharmaceutical company, or by farm owners hiring extra help. Most participants could give a litany of human error that occurs in everyday farming practice⁴². With regard to animal biopharming, the issue of human error may become more important in relation to the current liability laws, which assert that liability falls on those who break rules. Thus, securing quality labour was considered vital to the safety and economic success of animal biopharming by the farmers:

[Y]ou would be faced with employing top labour, let's put it that way. And therefore probably a substantially increased cost. I mean with our situation, I don't know if [other interviewee] said anything to you or not, but we've changed our labour situation down there quite dramatically because of just those sort of problems.

Q: ... So what kind of problems, just people not following the rules?

⁴² For example, gates being left open and penicillin-treated cows being unintentionally milked were commonly mentioned. The fact that penicillin cows are milked may be of particular relevance to animal biopharming, given that the separation of penicillin cows from the milk supply reflects a similar view of how GM cows may be treated.

[They are] just too slapdash you know, not, you know Saturday mornings being boozed and asleep and that sort of stuff. And it is pretty important, well it is very important that these things are kept separate. (Dairy farmer participant 4.)

One interview suggested that mistakes are particularly prone to happen on farms with many employees. Changes in shift times and more people on the farm mean that communication becomes difficult and mistakes are made. Interestingly, the point relates to the organisational nature of dairy farming rather than anything specifically related to animal biopharming itself. Thus, the farmer's focus in relation to risk was derived from a social perspective, rather than focused simply on the technology itself.

Some farmers mentioned the example of cows being milked that were not meant to be, simply through lack of communication or concentration.

It's a little bit like keeping antibiotic milk out of the main lot, you know. You are watching it all the time to make sure it doesn't happen; every now and again it does happen.

Q: How do you avoid that, [are] there steps that you can take to avoid it?

Yeah there are steps, you mark the cows and you milk them in test buckets and that sort of thing, but yeah it is always something to keep separate.

Q: What... leads to the mixing with the cows?

Well it would just be through the marking coming off, or you know just someone who has just sort of been busy putting cups on cows and just accidentally missed one or something. (Dairy farmer participant 5).

In fact, the potential for human error in milking cows was considered important enough for all farmers to suggest that GM cows be kept entirely separated from non-GM cows, at the very least in different milking chambers.

You would either have to do the whole lot or none at all wouldn't you? It would be very hard on a larger-scale farm to keep, I don't know how many cows you'd be looking at, but say it was ten cows for example it would be very hard to keep them separate on a farm from seven hundred other cows for example. You would still have to put them through the shed and milk them. (Dairy farmer participant 5).

Another comment from an interview further illustrates this point:

You know just the physical thing of keeping the milk separate alone would be quite substantial. I mean we do it now, with, as you say, penicillin milk and colostrum milk and all that stuff, but you know you are not too worried about a tiny little [bit of] cross infection. Well you are with the penicillin milk but, with the rest you are not. Admittedly the milking machines are getting a lot smarter so you know you have got bullets of air and stuff that you can blow through them so that you can clean them out. But, yeah, you are dependent on labour and things; I would see that as being a major problem (Dairy farmer participant 4).

Human behaviour/error and the implications for risk assessment

Most of the farmers assumed that human error and influenced behaviour is inevitable. Parallels can be found with Wynne's studies. Because lay knowledges' are generally more adaptive and flexible to 'physical and social worlds' they are less threatened by 'ambiguity and contradiction' than traditional scientific knowledge (Wynne 1996, p.299). Likewise the farmers in the interviews for this thesis generally accepted that environment and human behaviour cannot be completely controlled. Hence, their social world has been ordered to work around and adapt to this problem. From the interviewees' perspective it is not controversial to state that unexpected events and behaviour occur. Risk assessment should work from this assumption also.

A similar point is made by Marvier and Acker who list several examples of human error in the containment of corn to suggest that risk assessment should include the inevitability of human error (Marvier & Acker 2005, p.101). As they suggest, "...smart, highly trained, and conscientious people make mistakes, and those mistakes may be repeated and go unnoticed for years" (Marvier & Acker 2005, p.102). Therefore, in order to adequately and accurately assess the risk of animal biopharming, assessors must accept that behaviour and environments cannot be entirely controlled.

Economic incentive to flout rules

One farmer suggested that rules are most often ignored when there is an economic incentive not to follow them.

...the only concern that I have is that sometimes in New Zealand they want to prescribe the rules but they don't have the economic driver behind [it]. And so people skip [the rules]... I've never been in this field but you know like...effluent disposal, they think "oh this will do", you know. The rules are that strict, but if we do this and this, it might be alright. (Dairy farmer participant 3).

In the case of animal biopharming, this could be particularly important, dependent on the ownership structure of the operation. If a farmer owns the operation and is responsible for paying to ensure that all controls are met, the following of controls may be particularly influenced by economic factors. This is of particular concern given that the production of pharmaceuticals will most probably be isolated to one type of pharmaceutical per farm⁴³. Thus, the farmer is heavily affected by the international demand for that type of drug. If a downturn in the market occurred, or some other drug was supplied as competition, there may be a higher chance that corners are cut in order to remain competitive. Later in this chapter, the flexibility of production, or the inability to change back to normal dairy farming, will be discussed. These factors may also increase the risk of rule skipping.

Current risk assessment

The findings regarding economic influence on farmer behaviour may have implications for how risk is assessed. Instead of treating economic impact as an isolated issue, quantifiable in terms of cost and benefit, it may be pertinent to view economic impact as a factor that reaches into other areas of safety in animal biopharming. The farmers' comments illustrate that economic impact can be viewed as a risk in itself, such as economic loss to farmers, but also a factor that influences other areas of behaviour and risk, such as the ability, or willingness, to follow safety prescriptions.

Strict monitoring would be one potential way of avoiding such problems, however as stated in Chapter 4, the monitoring capabilities of MAF have been shown to be more focussed on cost-effective procedures (Nakhies, Loutit & Rogne 2003,p.50) and may not extend to extensive monitoring. This could particularly be problematic when animal biopharming becomes more mainstream, which would make monitoring more

⁴³ This will be discussed in the containment section of this chapter.

demanding and expansive, given the wider range of people involved. One farmer pointed the need to ensure the general safety of the product before it is in mainstream use:

Q: So how do you stop animals escaping at the moment?

I think being rigid before the animals are spread over, once they get into the next stage of [production]. I mean first you have your multiplication, and then you have your big group of people that breed these animals; it's got to be safe at that stage and very well controlled. But once you get to the next stage, it has got to be safe, or else you wouldn't want to buy it. (Dairy farmer participant 3).

Containment Factors

The previous chapter illustrated the need to contain bioreactor animals and possibly the GM constructs they incorporate. If animal biopharming is to be applied commercially and taken up by farmers, it is useful to see how the need for containment will affect farmers, and how farmer behaviour will affect the likelihood of this containment. The interviews highlighted several areas of concern regarding the ability to contain animal bioreactors and other materials.

Grazing patterns (off-farm winter grazing)

The common practice of off-farm grazing, particularly prevalent in the winter (in some areas of the country), may make containment more difficult. One farmer raised this point as an area of concern and a practical implication.

Your replacement stock are now very seldom grazed on your dairy unit, very seldom, and there is an awful lot of off-farm wintering. Well you wouldn't be able to do that.

Q: What is off-farm wintering?

Well over the winter the cows go out to grazing.

Q: Oh right, why don't you graze them on the dairy [farm]?

There [are] lots of reasons. You [do it] because the winter is the slowest growing of the year, and the spring is your highest intake of the year you need to carry some food ...some grass

through. ...You have got to calve your cows before your growth really starts. So therefore, you have got to carry grass forward. (Dairy farmer participant 4).

This may have practical implications for the controllability and containment of animal biopharming operations in the future. Depending on the size of the operation, it may be impractical to keep the cows on the same unit all year round. It is questionable whether the average farmer would have enough money to buy an adequately sized farm to compensate for the lack of grass in the winter. If the farmers were to graze GM animals off the farm in the winter, then additional safeguards may need to be implemented during transport of cows and measures may need to be in place to monitor the spread of GM material to soil microorganisms and possibly to other animals on those paddocks. At the very least, the farmer illustrates that strictly containing animals to one specific area may be a complex task requiring significant amounts of money and changes to normal farming practices.

DDT

The same farmer raises another grazing-related practice which may lead to the spread of GM animals off the one farm.

We graze all our animals off the property in Canterbury, but it is more for DDT, than anything else. Because the residuals of DDT in the land. (Dairy farmer participant 4).

DDT is insecticide which was widely used from the 1950s until it was eventually banned in 1970, when it was found to accumulate in the environment and settle in organisms within the food chain. Although the levels of DDT found in New Zealand soil are expected to be below the level that would cause health problems, the risk and undesirability of the chemical entering the food chain and further accumulation in New Zealand soils was enough to call for a ban (Boul 1994, p.257). Unfortunately, levels of DDT are still found in many farms across New Zealand, and, although decreasing, will remain for a long time (Boul 1994, p.271). The potential for DDT to enter the food supply influences the grazing patterns of cows, as the interviewee explained:

Q: Would you almost have to, for the health of the cows, graze them off the farm?

Well we do it in the winter, but it is not for the health of the cows... (Dairy farmer participant 4).

The interviewee went on to say that the residue is retained in the soil and over the winter the cows ingest a percentage of the dirt containing the DDT. This DDT is retained in the animal's fat, and during the spring when the cow is not consuming enough grass to meet demand, they 'milk their fat off'. From this process it is possible that DDT can enter the milk supply. In the words of the interviewee "...the world does not accept DDT in the milk" and it is therefore necessary in some areas to graze animals off the farm during the winter.

This again raises issues of transport and of potential dissemination of GM material, as well as the extra risks of DDT contamination of pharma milk. It will be important for controls to be in place to ensure that farms have low enough levels of DDT to ensure that off-farm grazing is not required. Currently testing is done on farms before they are converted to dairying, however the levels may need to be lower in the case of an animal biopharming operation, or they need to be able to afford a lower stocking rate, in order to avoid off-farm grazing.

Beyond this practical advice, parallels can, and have, been made between the introduction of DDT and the introduction of GM (*Scientists warn of DDT trap* 1999). DDT essentially restricts the freedom of dairy farmers to conduct certain farming practices. This could have been avoided if adequate testing of DDT's effect in soil and on living organisms was conducted before its adoption by farmers. In this light, vigorous testing of GM animals' effect on the soil must also be conducted to avoid negative repercussions in the future. As Dr Turner, a soil chemist at Massey University, suggested in a 1999 article for Dairy Exporter,

Nobody has looked at the soil implications...Most of the current interest is in health and food safety issues, but no one has taken into account that GE modified crops are likely to leave a genetic imprint on land on which they are grown (*Scientists warn of DDT trap* 1999).

This may be equally applicable to GM animals and may be particularly relevant given the evidence from these interviews, which suggests it may be difficult to contain cows or soil on one farm without great expense, time and energy.

Reliance on animals and the cleanliness of milk

Because it is likely that biopharm milk will need to be kept at a higher standard of cleanliness, the chance of animals becoming sick and disrupting production may be particularly concerning to farmers. The cost of veterinary care may be higher than normal dairy farm operations as the health of animals will be particularly important, and regular checkups will perhaps be required. It may also be necessary to hold extra animals in case an animal does get sick and adversely affect the economic viability of the operation. If this is the case, the disposal of excess milk may become a factor. Several interviewees suggested that the practice of spraying unused milk onto the paddock may have to be changed, particularly if this land is being grazed by non-transgenic animals as well. The chance of this milk affecting the soil composition may also be an issue.

Turnover rates of farms and employees

As stated previously, the PPL therapeutics field tests ended with controversy. The failure of partner company Bayer to continue funding of the operation led to the termination of the field test, but also highlighted important areas left unregulated regarding the operation. Questions such as what would happen to the GM sheep and land were left for the courts to decide (*Court Told Decision on GE Trial Site A Concern For New Landowner* 2004).

Interestingly, farmers could envision similar problems occurring as a result of the current climate of farming in New Zealand. One farmer suggested that the high turnover rate of farms and farm employees could leave problems for regulators. If land is bought and sold at a fast rate, or employees move from job to job at a high rate this could pose problems for rule following and adequate containment. Questions of whether animal biopharming farms or animals can be traded will also be relevant to risk assessment. One interviewee suggested that the current climate of high turnover relating to farm ownership and employment was particularly relevant to these issues of containment.

The interviews suggest that the same questions that arose after the PPL situation, such as whether GM animals can be traded or whether land can be used for both GM animals and non-GM animals, will inevitably arise given the social climate of farming

in New Zealand. The high turnover of farms could potentially lead to a wide spread of GM material or the selling of GM animals. Therefore, flexibility of production, whether a farmer can change back to non-GM farming or sell their animals or land, raises important questions that will have significant implications for the safety of animal biopharming. The interviews suggested that some farmers may not be interested in an operation which leaves little room for opting out. Most farmers found these questions of concern, as illustrated by the following questions of one participant:

What implications would [there] be? What can you do with those cows? Would they have a month of milk withholding and they can then join the main herd? (Dairy farmer participant 1).

Similar problems could arise from the nature of employment in the dairy industry. A 2002 a report showed that 76% of employees in the dairy farm industry had worked within the industry for over a year. However, only 28% had been at their job for more than one season (Shearle 2002, p.17). This indicates a high level of job turnover that will have to be addressed by farmers, or pharmaceutical companies, who hire help with biopharm animals. Training will be a high priority in order to ensure the safety of animal biopharming but the high level of turnover may make this more difficult and costly. One implication for farmers is that they may have to commit to longer-term employment under an animal biopharming operation. One interviewee suggested it would be particularly impractical for share milkers to be involved in animal biopharming because they tend to move farms every three or four years, which in his eyes would cause the containment and regulatory difficulties discussed above.

Who enters the farm?

As stated in the last chapter, there has been significant debate about the effect animal biopharming may have on soil. Questions of whether transgenes and their proteins can be transferred to the soil through animal waste are still regarded as debatable. If GM material can be transferred into the soil, it becomes clear that animal biopharming facilities will have to be completely segregated. The interviews show the cost of such an operation could be huge, and the practicalities of the operation nearing impossible.

Many farmers suggested that the need for segregation would be complicated by various farming processes that effectively require traffic through the farms. The potential for hay bailers and land fertilizers to spread soil from one farm to another was identified by the interviewees.

I can see a problem like with the likes of hay bailers and stuff, because there is always a bail left in the chamber. Carrying feed off one farm onto the next; I don't know if that would be an issue or not, but that is in fact what happens. You know the big forage harvesters always have grass hanging off them and things like that. They may well have to clean their equipment before they left the farm. (Dairy farmer participant 4).

It is questionable whether workers applying fertilizer and hay-bailer operators will find time and the economic incentive to clean their equipment each time they exit the farm. An article in *Nature Biotechnology* also questions the wisdom of presuming farmers will follow such meticulous cleaning standards, this time in relation to GM plants, however the point is applicable. "Can we reasonably expect farmers to clean their agricultural equipment meticulously enough to remove all GM seed?" (*Nature Biotechnology* 2002, p. 527).

Getting rid of carcasses / replacements

As stated in the last chapter, the number of animals needed by an animal biopharming operation will vary according to what type of pharmaceutical or nutraceutical is being produced, and the levels at which they are present in the milk. However, there is a good chance that fewer animals will be needed than normal dairy operations. If this is the case, major implications for how dairy farmers run their operations are evident. Several farmers were concerned about the ability to dispose of excess animals in terms of economic cost and containment issues relating to soil. One farmer suggested the cost could be significant, as some farmers' income, including share milkers', is derived from the culling of animals and sale of bobby calves:

One of the other problems if the beef at the end of their life cycle is not acceptable in the meat trade, you have got a problem there getting rid of them. ... The lack of income, you know the loss of income from them, because it is about, what is it? I don't know. What is about 20% of the farmer's income that is cull cows and bobby calves and things like that. Yeah it is a little bit less than that, but it is getting up to that figure.

Q: Ok so what, I mean, is there any way to get around that?

There again it becomes a cost figure. I mean you would have to have those animals slaughtered and destroyed in some manner. And there again it becomes a cost factor. Therefore it might be better for someone else to own those animals, like whoever is doing the project. (Dairy farmer participant 4).

This suggests that the cost for a farmer to individually own one of the operations may be too high. Another issue with culling animals concerns the environment. If animals are to be buried on the farm, then the water table must be considered, as one farmer illustrates. The potential for animal waste and pollutants to run into the water system may be more likely the larger the number of animals that are being disposed:

...ten metres below us is water. We don't want to have rotting decaying animals going into the water system here. The underground water... that goes across Canterbury; and so if we can burn them, and generally it takes two or three burns to actually get the animal totally done, but it means it is not rotting and being buried and all t[he] bad products [are] getting into the water system. (Dairy farmer participant 1).

Similarly, whether the animals are buried or burnt, there could be flow-on affects to other farms:

Q: what about with, like, material you've burnt, the cows ... is that like what you are talking about it could run off into another farm?

...every farm in this district is linked through water, because of underground rivers. So anything we do here could be affecting four or five people down the road. Because of all the water filtering underground. So yeah. (Dairy farmer participant 1).

Selling waste for use in animal feed

Because of the cost and inconvenience of culling animals, there is a possibility that offspring of animal bioreactors not used for pharmaceuticals, or which do not express the appropriate proteins, will be allowed to be used for non-human consumption such as animal feed. It is likely that this will at least be requested by those producing transgenic animals (U.S National Research Council Committee on Defining Science-based Concerns Associated with Products of Animal Biotechnology. 2002, p.54). If this is this allowed, problems could arise. As with the corn industry in Starlink case, in which corn had approval for animal feed but not human consumption, it is

questionable whether the New Zealand dairy and beef industry has the ability to determine whether the animals they process are transgenic or not. It may mean that meat works should be provided with adequate testing facilities. Thus, a wider range of responsibility for safety may need to be cast if animal consumption is allowed.

Flooding

Another area identified by farmers that may affect the containment of animals is flooding. As it is common during and after floods for animals to mix, all the farmers suggested that animal biopharming should not be permitted in common flooding areas. An interviewee described the level of disorganisation that occurs during a flood, in which normally controlled environments could easily be disrupted. The ramifications for containment are obvious:

It would be too risky to have a farm like this in a flood place. Where all of a sudden your farm is coming under water and you have an hour to shift your stock and it might mean open the gate let them on the road, and mix them with neighbour's cows to get out of the flood waters. That would be a huge risk. But you wouldn't have a farm like this on the flood plain. You know, when you get your consent to have a farm like this that would be an issue that would be talked about then. (Dairy farmer participant 2).

The interviewee illustrates the need to consider the local placement of the farm conducting animal biopharming, when considering its ability to contain animals. The implication of this point is that only certain farmers in certain areas will have the option of animal biopharming.

Characteristics of the land

The farmers were certain that the positioning of the farm and its soil types would be important. Whilst risk assessors may be aware of this, it does point out an area in which local knowledge of specific environments may be useful in determining the safety of a location for animal biopharming. This is particularly the case if soil is a factor. The following quote from a farmer illustrates the detailed local knowledge farmers hold:

It would probably have to be somewhere that is free draining, that doesn't get gluggy soils so the water can get through the soil as quick as it wants but it doesn't get down to the actual water

table for twenty or thirty metres. So it has a huge buffer zone. You wouldn't want it clay, because clay soils... the rain doesn't go through them, it goes off them. So the soil structure, you wouldn't want stones like what we have got here because the water goes through too fast. Taranaki has got good organic soil...good drainage, good soil...Probably not anywhere around a river bank. Getting into some of these deeper country soils around here. You wouldn't want somewhere around Leeston way where it's low. Ellesmere is getting quite salty, salty stuff in their soils. You wouldn't probably want it, you'd want it in a high rainfall good rainfall area, you wouldn't want it to be irrigated. (Dairy farmer participant 1).

The same farmer questioned current controls that demand a plant-free strip between fences in the farm. The participant argued that the common practice of maintaining a riparian strip between rivers and farm land could be jeopardised, hence raising the chance of leaching of GM materials or animal waste which contains GM materials.

My own thoughts on that is, "why do we have riparian strips between rivers?"

Q: what is that?

Next to any creek river or anything, you leave five metres of land and you leave it to have nice long grass on it, and then you put trees in there. Because anything that leaches across, before it gets to that water way, everything that is over there is sucking all the nutrients in the soil so nothing can get in the river. (Dairy farmer participant 1).

However, there may be a trade-off between riparian strips to protect waterways from contamination, on the one hand, and the visibility of animals as an aid to containment, on the other. If a riparian strip is required, trees that lie between the fences containing GM animals may make escaped animals less visible. In order to maintain the safety of animal biopharming operations, these issues will need to be addressed.

Economic Factors

Flexibility of production

As discussed above, the need for flexibility of production may impact on the safety and containment of animal biopharming in New Zealand. It also suggests that there are significant economic risks for farmers who choose to invest in an animal biopharming operation. The ability to revert to normal dairying was questioned by several farmers. This could severely affect the desirability of such an operation. The following participants' comments illustrate the ways in which the current dairy

industry context could affect the desirability and economic impact of biopharming for a farmer. He suggested that the power Fonterra⁴⁴ holds to accept and reject milk may particularly affect investing in animal biopharming for the farmer, given the chance the operation may not work out.

Well that is a risk because you are not sending your milk to a mainstream company as much. I would sort of relate to someone opting to take their milk away from Fonterra and to one of the small companies that are starting up. What happens if that one factory burnt down? Where is that milk going to go for the next two or three months? Because that factory is out of commission.

Q: Can they go back to Fonterra?

Well Fonterra doesn't, if they've said "bye bye Fonterra", Fonterra aren't going to be too kind to them and get their milk back. Unless they might be short of milk and want the milk, but they have the capacity they could say, no, sorry we don't, we can't handle your milk. It would be a risk similar to that. Because you can't start up again. (Dairy farmer participant 2).

Overseas pressure

Another economic risk of animal biopharming relates more generally to the demands within the international market for farming as it currently stands. The potential for overseas markets to require certain procedures from farmers, or place "non-tariff trade barriers" on New Zealand farmers could affect the New Zealand dairy industry significantly. Even if certain types of animal biopharming are found by New Zealand regulators to be safe, and hence requiring minimal controls, overseas markets may force strict procedural standards regardless. These standards could potentially affect non-GM farmers as much as GM farmers if international markets are concerned about cross contamination and thus require non-GM farmers to perform procedures or tests to insure they are not contaminated. The following comments by participants identified these issues:

... I would be more concerned about the market. Like the 'marketplace' in inverted commas. Whether it be the whole of the New Zealand dairy industry, or the world dairy industry.

⁴⁴ Fonterra Co-operative Group Ltd is a multinational dairy company, owned by 11,600 New Zealand dairy farmers. Shareholders make up over 95% of New Zealand dairy farmers (Fonterra 2006).

Whether they see it as, you know, another form of tariff that can be slapped upon us, because they do it with all sorts of other things.

Q: Ok, another form of tariff as in?

Like, “you have got GM milk we won’t take it”. You know you are also farming GM milk, there could be some type of contamination therefore “we won’t take your milk.” ...I mean that has happened, I mean a lot of a milk problems are really only driven by tariffs. Unofficial tariffs, they are saying you have got to have this and you have got to have that, just to make it a little harder for us to get in there.

Q: So it might not just be the New Zealand government...

No no no no. It could well be the marketplace. And I see that is a bigger problem than New Zealand [controls] quite frankly. (Dairy farmer participant 4).

Another interview raised a similar concern:

Yeah, that is right, the international influence from overseas. The way we present our cows. The inductions make the cow abort her calf two to three months before she is supposed to. You know [those] procedures [are] a real no no. So they will say we prefer not to have your milk or we won’t buy your product because you dock the tails on your cows and abort cows prematurely so that is how big an influence the overseas market has. So that is probably the biggest risk that we have talked about today is what we are talking about now. (Dairy farmer participant 2).

Size of herd-milking and cost

The cost of creating facilities to transport and milk smaller herds was suggested as an interesting implication of animal biopharming. Current milking facilities are designed to milk hundreds of cows; they cannot, according to the interviewees, be used on small herds, as the quantity of milk obtained from them would not be enough even to push through the machinery. This implies that milking small biopharm herds would require the design and installation of new milking facilities, significantly raising the cost of the operation and the amount of investment in sunk costs.

The interviewees also suggested that the transportation of significantly smaller amounts of milk will result in additional costs and infrastructure requirements:

Yeah you are going to have to have some form of storage in collecting it separately. Like a milk tanker comes in here and picks up twenty thousand litres of milk, if you are going to, every day, if you have got another little group of ten cows, you know, you'd have to pick the milk up at least every second day to keep it right. And ten cows times 30 litres a day in the peak for example, which is 300 litres of milk a day from that little group of cows. So you might have to have, you'd have to have a little tanker that picked up six hundred litres of milk every second day. (Dairy farmer participant 5).

What are neighbouring farmer's rights and who is liable?

The question of liability for damage to neighbouring properties raises another set of economic issues. Should neighbouring farmers be expected to deal with the extra work and cost of monitoring if a GM cow from another farm escapes on to their land? The rights of neighbouring farmers may need to be discussed before any commercialisation of biopharming occurs. Also, if GM material is found to be transferred into soil, this could potentially lead to a lower value of land for neighbouring farmers (*Scientists warn of DDT trap* 1999). This raises the question of liability. On the other hand, if a GM farmer is held liable for escapes onto neighbouring farms, it may be too costly for many farmers to own this sort of operation or pay for adequate insurance. Several farmers argued this would be the case:

No they wouldn't be able to [own cows]. Not in this sort of world... for instance if you would end up in the environment court. A couple of hundred thousand later. (Dairy farmer Participant 3).

Scenarios

There are several scenarios for the future of animal biopharming in New Zealand. Each will have varying implications as illustrated by the interviews. This section will briefly evaluate the four scenarios (Farm manager, Farmer-owned, Farmer-subsidised and Coalition of Farmers) and the implications they may have. A more detailed discussion of the implications of the last scenario, Coalition of Farmers, for the relation between local government and the HSNO Act will be discussed in order to illustrate where detailed local knowledge may provide useful information. It is important to note that the risks of soil contamination, grazing patterns, the lie of the

land, human error, culling of animals, flexibility of production and the effect of international markets are generally the same in each scenario.

Farm manager scenario

Containing the modified animals adequately will likely have a strong economic impact on the operation. Adequate fencing, milking facilities, cleaning equipment, security and milk transportation systems all suggest the cost of running such an operation will be high. This raises questions as to whether dairy farmers will be able to run this operation under their own funding. It seems most likely that a farm management system will be operated in which farmers do not own the farm or animals. Risks and implications specific to this scenario include:

- 1) The attitude of farm managers may mean less commitment to following strict controls.
- 2) The length of farm management contracts and job turnover rates may be an issue particularly as training will be vital to operational safety.
- 3) The farmer may not see large benefits from the operation, beyond what farm managers on conventional farms receive.

Farmer owns the operation

It unlikely that farmers will have the economic resources to start their own animal biopharming operation. However, there is a small possibility that controls will be minimal enough, particularly if the product is considered GRAS, that farmers may own the operation. Risks and implications specific to this scenario include:

- 1) The ability to buy and sell a farm once it has been used for animal biopharming may be limited.
- 2) The turnover rates of farms and farm employees will affect containability and will have to be controlled for: however there may be limited legal mandate to do this.
- 3) The reliance on one product could lead to economic vulnerability for the farmer.
- 4) Farmers may be influenced by external economic forces to cut corners in following rules.

- 5) The employment of staff will have to be monitored to ensure quality and reliability. This could have implications for the rights of farmers to choose who they hire.

Farmer owns the operation but is subsidised for containment and safety costs

For animal biopharming to be accessible to farmers, it is likely that containment and management costs would need to be subsidised by a larger company. If this is the case, the operation may be more affordable and available to farmers. Risks in this scenario will be similar to those of simple farm ownership. However, it is likely in this instance that more farmers will opt into animal biopharming operations. Therefore:

- 1) Monitoring and maintenance of biopharming operations, by MAF, may be more time-intensive, and may be prone to less scrutiny, given the wider scope of its use.
- 2) The implications of risk or costs associated with animal biopharming will be dispersed more widely given the wider scope of its use. For example, non-official tariffs from overseas may be blanketed across the dairy industry if animal biopharming becomes a relatively mainstream dairying option within New Zealand.

Coalition of farmers within a geographical area

In an interview for the scoping section of this thesis, a senior member from NZTE suggested another possible scenario of management. A number of farmers within a designated area could form an animal biopharming coalition. He suggested this could be similar to agreements currently made between organic producers within some regions of New Zealand. A key implication of this scenario may be the conflict between local government and ERMA.

As a coalition of farmers would encompass a larger area, the effects of biopharming on the land may be more intensive and further-reaching. This may lead to the Resource Management Act (RMA) being enacted by local governments to ensure stricter standards of containment than ERMA would require, hence leading to potential legal conflicts between local governments and the ERMA decision. The

main tool for influencing decisions from a local government's perspective would be the RMA, in which a precautionary principle has been ruled by courts to be inherent. On the other hand, ERMA's use of the precautionary principle is optional (Terry 2004, p. 17). Simon Terry suggests the government has not yet explored the implications of these conflicting standards of precaution. As ERMA's process is suggested to be the 'gold standard', where in actual fact it is not legally bound to make precautionary decisions, a conflict between local expectations and legal mandate could arise (Terry 2004, p. v). Interestingly several councils have already symbolically declared their jurisdictions 'GE free'⁴⁵.

The potential for conflict between local governments and ERMA rulings is further discussed on the website of the Ministry for the Environment, which suggests that whilst it is possible for local governments to use the RMA to control GM in their region, this would be very difficult to do. The website states that the issues surrounding GM safety are "highly technical, meaning that councils are unlikely to have the skills to deal with these issues" (Ministry for the Environment (a)). As ERMA is a specialised body designated to perform risk analysis, MFE suggests it will be difficult for local governments to offer any legitimate reasons for GM not to proceed if approved by ERMA. Such a viewpoint is contradicted by findings from the interviews within this thesis, which suggest that individuals will hold unique knowledge on how animal biopharming could affect their particular local environment. For example, soil type, vulnerability to flooding and grazing practices will all inform the safety of animal biopharming. Thus, local governments may have better access to relevant knowledge of the land and social practices within a region than would ERMA.

Several interviewees assumed that the RMA would be available to settle local complaints. The following participants' comments illustrate a need to clarify the role of the RMA in relation to animal biopharming before commercial applications are considered or approved:

⁴⁵ These cities are Nelson, Napier and Waitakere. The general Northland area has been declared GE free by the Northland Regional council and local mayors.

We are covered by the RMA anyway. Because [with] the Resource Management [Act], I wouldn't be allowed downstream effects, it shouldn't have [an] effect on me. The Resource Management Act will protect you there because there has got to be a tolerable land use. (Dairy farmer participant 5).

Conclusion: *Who Benefits?*

Most farmers pointed out that given the considerable costs of containment and controls, it is most likely that an animal biopharming operation will not be owned by dairy farmers. There are potential benefits to this situation, particularly because the farmer is shielded from negative economic impacts and may be less likely to be influenced by economic pressure to cut corners⁴⁶. However, it is useful to question who benefits from this arrangement, and whether such an arrangement can really be considered to provide a potential dramatic increase in farmer returns as some of the previous interviewees and literature have suggested. One farmer spoke of the reluctance farmers would have to simply manage operations:

A] farmer in general, wants to be part of it... in general you want to be in control of your own environment. And I think in general once you have sort of a lease agreement type thing, you are not in control of your own destiny anymore, you just become an employee of that company. (Dairy farmer participant 5).

As an employee of a company it seems unlikely that farmers will share in the purported potentially large profits of biopharming that a company could make. Perhaps there can be a higher wage offered for the added work to ensure safety, but beyond that, there may be no incentive for the larger company to offer further benefits to the farmer.

This also raises questions about the extent to which New Zealand as a whole would benefit from such an arrangement. If the bulk of the profits accrue to a foreign-owned pharmaceutical or biotechnology company while New Zealand bears the cost of any market devaluation suffered by its conventional and/or organic production, or absorbs the liability from unanticipated harms to others or to the environment

⁴⁶ However, this is debatable, it is perhaps no less likely that larger companies will be influenced by economic factors to cut corners or, inadvertently or not, put pressure on the managers to do so.

resulting from the operation, there may be reason to question whether this can be considered a 'benefit' to New Zealand.

Size of operation

As it is reported that relatively few cows are needed to produce the world's demand for certain pharmaceuticals, it is also questionable how many farmers will be involved in animal biopharming operations. Unless New Zealand runs multiple farms producing many different pharmaceuticals, it is difficult to see how this technology can benefit dairy farmers dramatically, as otherwise only a very small percentage of farmers are likely to be involved in any way. Again, it may be useful in this light to question claims that animal biopharming can revolutionise farmer returns.

Characteristics of the Land

The interviewees note that the type of land and soil will be crucial to avoid flow-on effects to other farms, dangers such as flooding and off-farm grazing because of DDT or winter conditions. Therefore, the option of animal biopharming will again be limited to a small number of farmers with the appropriate land type. It is questionable whether it can be claimed that the dairy farming industry will benefit from animal biopharming if only a small number of dairy farmers, and perhaps the even smaller numbers supplying the specialist infrastructure required, can benefit.

Risk/Cost/Benefit analysis in Risk Assessment

The limited benefit that animal biopharming is likely to hold for dairy farmers means it is useful to reconsider current assessment processes. As stated in an earlier chapter, ERMA undertakes a risk/cost/benefit analysis when considering applications to conduct animal biopharming. ERMA has stated that it will consider the distribution of these benefits, distinguishing between public and private economic benefit (New Zealand. Environmental Risk Management Authority 2005 (b)). The findings from this chapter suggest that using local knowledge may be useful for considering *who* benefits from an application, and whether these benefits are relevant to New Zealanders. These interviews have highlighted that local knowledge can offer useful information in determining the answers to such questions. In the case of animal biopharming, it is likely that overseas companies will benefit from these operations if

they are successful, while it appears there will be fewer benefits for New Zealanders managing the operations.

It is not claimed that these interviews are a representative sample of dairy farmers, and the interviews have not been intended to canvass “New Zealand dairy farmers’ views” on biopharming. Rather they have been used to explore the usefulness of the approach to risk assessment outlined in this thesis. In fact, they have been remarkably productive in raising a diversity of potential risk factors relevant to animal biopharming. This suggests that focusing on what has here been called ‘local knowledge’ may enable the identification of areas of risk that may go unidentified in traditional risk assessment processes. Whilst few of the interviewees had prior in-depth knowledge of animal biopharming, they were able to adapt their environmental and social knowledge of dairying to the topic. Such a finding is worthwhile in itself, as it suggests that it is not only policy makers and scientists who are ‘experts’. It may be important in this light to offer some avenue of participation for people such as the interviewees to discuss future technologies and their risks, before they reach the level of application. Beyond that, a tool for locating and eliciting different types of social expertise should be adopted by ERMA when assessing applications. Such knowledge is too valuable to rely on participant initiative; it must be identified and sought after if risks are to be adequately assessed.

Chapter 7: Conclusion

This thesis has analysed some of the social dimensions of animal biopharming. In doing so, it has taken a different approach to current risk assessment processes, which limit the ability of members of the public to contribute practically. Under the current model, the public is isolated as value holders, where the experts are left to define the bounds and nature of risk. Such an approach ignores the complexity of the social and environmental world animal biopharming will enter in its commercialised form. The findings from this thesis suggest that people outside the traditional bounds of expertise hold valuable information on the social context the technology will enter. They can help practically in identifying risk, but also serve as a reminder of the complexity of risk within uncontrolled environments.

In this concluding chapter, I will summarise the findings of this research. I will then explore the implications of these findings for the concept of local knowledge, the nature of risk assessment and the role of the public within it. Following this, general recommendations will be made for how risk assessment should proceed in New Zealand. Lastly, the limitations of this thesis will be discussed, as well as opportunities and avenues for further research.

Summary of findings

Through scoping relevant literature and in-depth interviews with policy makers, regulators and developers, it was possible to identify several areas in which animal biopharming in New Zealand was likely to develop in the future. On this basis, it was possible then to interview experts in the field of dairying on the risks that animal biopharming might hold for them, and what risks their practices might hold for animal biopharming. These interviews proved highly informative.

Firstly, it became clear that farmers viewed human error and flexibility in rule-following as a reality of their social world. Although they did not suggest that farmers held rules in disregard, the environmental and social elements that influence behaviour were stressed within most interviews. For example, economic pressure, social disorganisation and general elements of human error were considered by farmers to be influential on the future safety of animal biopharming, but also a fact of

everyday life as a farmer. Multiple examples were offered to illustrate mistakes occurring on the farm due to these factors.

Other practical areas of risk were also identified. Both farming practices and environmental factors will affect the containability of animal biopharming according to the interview participants. For example, normal grazing management is likely to affect the viability of containment of animal biopharming if not controlled. The common practice of off-farm grazing may need to be restricted, which in turn would limit the number of farmers for whom this technology is feasible. Other individuals' behaviour will also have to be monitored, for example, hay bailers and those who apply ground fertiliser may have to change their practices also. Regarding environmental factors, the chance of floods or the characteristics of soil were all raised as factors to consider when analysing animal biopharming. Thus, the thesis found that in-depth knowledge of local environment and farming practices would be important in the risk assessment of animal biopharming.

Economic factors were also mentioned as both a risk in themselves and an influence on rule-following behaviour. The limited flexibility of production was considered a danger of animal biopharming, and the high turnover rates of farmers and farms as a risk to its safety. It was also suggested that the costs of animal biopharming and the amount of controls this would require, for example, the culling of excess cows or the building of unique milking facilities, may leave ownership out of the reach of most farmers. Farmers were also concerned beyond their immediate environment to the international markets, which could be hostile to milk produced in proximity to biopharm milk or require safety procedures beyond what ERMA may mandate that could add significantly to the cost of production. In isolation, these factors can be considered of risk to the farmer; however, farmers also pointed to the possibility that economic pressures would lead some farmers to 'cut corners' in a way that could undermine ERMA's mandated risk-minimisation rules. This focus on behaviour marks a contrast between technological approaches to risk and the social perspectives of the farmer informants.

Thus, beyond the practical implications, for instance, the need to consider the practicalities of likely controls, such findings suggest a different worldview between

risk assessors who look to control environments and behaviour within risk/cost/benefit equations and forms of local knowledge that accept and adapt to ambiguity within their everyday world. In this sense, the findings further validate and support the writings of Wynne (1996), and others who stress the differences between local and expert approaches to uncertainty. With the case study of Cumbrian sheep farmers, Wynne illustrated the implications of attempting to standardise unique environments, as the scientists did. The solutions scientists devised were found to be impractical when entering the sheep farmer's social and environmental world. On the other side, farmers were shown to be more willing to adapt their knowledge to the ever-changing environments that technology enters (Wynne 1996, p.40). As Wynne suggests, and these interviews illustrated, "ambiguity and contradiction are not so much of a threat [to farmers], because control and manipulation are not being sought or expected" (Wynne 1996, p.41). Therefore the challenge for those introducing a new technology into particular environments is to balance universality of the product and the demands of a particular context or locality (Wynne 1988, p.153). Those who emphasise or promote the benefits of animal biopharming may be similar to the scientists in the Cumbrian case, who assumed that their standardised knowledge was adequate and applicable to the unstable social and environmental world of sheep farmers. Animal biopharming may have the potential to yield great benefits, however the interviews suggests this will require a highly controlled environment. Thus, the conditions required for success may conflict with the environments animal biopharming is to enter.

Implications

This thesis has reflected many of the concepts and principles found in Wynne's Cumbrian study. For example, as stated, the adaptability of local knowledge, and the willingness to apply this knowledge to new situations was well demonstrated by interview participants. However, as Wynne studied hazardous materials that had already dispersed into the environment, an important implication of the research conducted here is that it illustrates the benefits of applying local knowledge before a technology or hazard has entered the social environment. Although animal biopharming is not yet commercial or widely used in New Zealand, the interview participants were able to offer practical information on potential future risk. The findings suggest that local knowledge is in this way applicable to risk assessment

situations, rather than merely useful for after-the-fact analysis. A more proactive approach than is currently used by risk assessors, or explored in the local knowledge literature, may be required to identify and extrapolate local knowledge earlier. Instead of passively waiting for those with valuable local knowledge to lobby for their own representation, typically after they feel their knowledge has already been ignored (for example, popular epidemiology), this approach would actively seek out local knowledge to use as a tool to avoid hazard, rather than merely reflect on the causes of hazard. In other words, studies should not only seek to prove the absence of recognition of local knowledge, and the negative effects of this, but also explore whether and how relevant local knowledge can be elicited or mobilised to prevent such negative effects. Likewise, risk assessment processes should not rely on the initiative of those holding local knowledge to come forward through public submission (particularly as often those holding this knowledge are unaware of its relevance) but actively seek out this knowledge. This study has shown that such proactive research can yield practical and useful results.

As well as supporting the concept of local knowledge as a tool for risk assessment, the findings from the interviews also reflected other themes of local knowledge discussed in the literature review. For example, the literature suggests local knowledge does not necessarily relate specifically to a physical environment. Interviewees for this thesis did offer considerable knowledge on physical location and its implication for animal biopharming, but a large amount of the interviews stressed non-physical factors which could be of implication and risk. Attitudinal, behavioural and economic factors were all cited as potential areas of implications, drawn from the interviewees' own experience and knowledge.

In terms of the character of local knowledge, such findings support the view that local knowledge is more specific than common knowledge, reflected earlier in the literature review, and thus must be used pragmatically rather than simply as a tool to enable mass public involvement. For example, some farmers recommended that truck drivers could offer more knowledge on milk transportation given their day-to-day experience, and in doing so, implicitly acknowledged the experiential and contextual nature of local knowledge. Whilst the farmers did hold knowledge that was traditionally passed down, the findings also suggest a more adaptive and complex

form of local knowledge than a conception of traditional and homogeneous knowledge allows. Each farmer offered differing and unique forms of knowledge based on their own experience and perception of social environments. This suggests that risk encompasses a wide spectrum of factors for farmers, and perhaps offers an avenue to better assess social risk practically.

As stated in Chapter Four, ERMA has struggled to find practical ways to measure social impact; these interviews suggest an avenue toward achieving this. Local knowledge will not only help risk assessment in locating the practicalities and implications of physical controls and technologies, but can also help us understand how social networks interacting with these controls and technologies will affect and be affected by them. By including social factors within the conception of risk, interview participants were able to identify areas of risk that may normally go unnoticed under traditional risk assessment. For example, the likely factors contributing to human error should be accounted for when assessing the risk of technology, even though these factors are not exclusive to the technology itself. It is often the combination of the technology with these factors that constitutes risk. Thus, although not technically detailed, this flexible and pragmatic approach to risk, shown by the interview participants, may be more useful than an exclusively scientific-technical approach. The approach also shows that, contrary to the deficit model, a lack of knowledge regarding 'scientific fact' involving the technology did not disqualify the participants from making a significant contribution to its evaluation. This finding should further support the literature of the 'public understanding of science' which discredits the arguments purported by the deficit model.

At the very least, the findings suggest that risk should not be compartmentalized into purely technical and social categories, but that both these factors impact on each other. Local knowledge can be used as a useful tool for identifying this connection. For example, the technical risk of gene transfer will be influenced by the social behaviour of farmers, including off-farm grazing and farmer attitudes to rule-following. Such findings suggest a re-conceptualisation of risk may be required of risk assessors. The current system limits the majority of public participation to normative questions and site-specific applications, falsely compartmentalizing areas of risk. Submissions from the public on field-tests have

been rejected as ERMA interprets public concerns more in the light of ethical concerns or “firmly held beliefs” than concerns over the practical considerations and safety issues regarding commercialisation. . This conclusion by ERMA, that concerns from the public are values, and general in nature, ignores that the public may have more than merely values to offer the debate. As Levidow and Carr (1997) suggest, official discussion of ‘ethics’ often allows an exclusion of other views and problematic concerns from the public. It is a similar demarcation of the public and science world that Wynne and Irwin (Irwin & Wynne 1996; Wynne 2001) point to as oversimplified:

...the relationship between science and the public may not be so straightforward as suggested in the conventional treatment which assumes a clear boundary between ‘facts’ and ‘values’ (Irwin & Wynne 1996, p.3)

The findings suggest that members of the public should be able to contribute practically to technical decisions about a technology because the dimensions between technical areas of risk and social areas of risk are blurred. Decisions over field-test applications should be able to utilise local knowledge of potential future social implications. This will not only better include the public, but also, allow for better decision making.

There may, however, be political difficulties in utilising local knowledge in risk identification and regulation. Beyond the politics involved in gaining recognition for a legitimate role for local knowledge in risk assessment, local knowledge itself can become politicised. As the interviews and the literature on local knowledge suggest, the views amongst individuals holding local knowledge is neither homogenous nor automatically useful. Farmers interviewed had different opinions on the risks involved in animal biopharming: for example, some felt that farm managers would be inappropriate to run the operation, whereas another felt them ideal. It is for this reason that local knowledge could potentially be used as a political tool within the debate over animal biopharming. If local knowledge is considered legitimate expertise, it may then be used to add legitimacy for both sides of the debate, much as other forms of expertise are, and focus could be pulled away from risk assessment. A scenario similar to the one Beck (1992) describes in *Risk Society* could encompass the pursuit of local expertise, in which competition amongst those claiming access to ‘legitimate’ local knowledge leaves no clear answers, and further disillusion the public. A

challenge for risk assessors will be to identify ways of identifying relevant local knowledge, without creating this scenario.

Recommendations

Whilst identifying practical areas of concern, the findings also suggest the general point that policy makers and scientists are not the only legitimate ‘experts’ within risk assessment. It is in this light that risk assessment and policy within New Zealand should move forward. Public participation need not be limited to normative discussion, nor does risk analysis need to be limited to scientific input. As this thesis has illustrated, local knowledge can be useful practically in decisions and assessment regarding technologies, even if this knowledge does not relate specifically to scientific details of the technology. It is important that risk analysis takes an active role in identifying ‘experts’ outside the traditional realms of science and policy in order to conduct accurate risk assessment. The approach adopted by this thesis may be a useful tool for risk assessors to accomplish this. Such an approach offers an avenue to more accurate assessments of risk, and perhaps allows for better risk minimisation.

This does not require a radical reshaping of the current *Methodology*, by which ERMA is currently bound. The *Methodology* allows for expert consultation, but does not offer a definition of what constitutes expertise. For example, Section 17 of the *Methodology* states, “The chief executive of the Authority or the Authority may appoint experts to review the information contained in applications, including the risk assessments and proposals for risk management”. In fact the *Methodology* suggests that ERMA must consult experts when considering decisions; Section 2(c) states:

[ERMA m]ust review and verify information contained in applications and submissions from the public or, where appropriate, engage expert bodies to conduct the review and verification or to provide additional information so that the Authority may be expertly informed for the purposes of decision-making.

In this sense, including local knowledge may only require a widening of ERMA’s understanding of ‘expert’, and perhaps a more proactive approach toward both identifying ‘experts’ outside of the traditional areas and eliciting information from them. Relevant holders of local knowledge could then be included in decisions over

risk and may be able to offer useful information on controls designed to manage risk as ERMA is required to do.

This study has also pointed to the need to involve the public earlier in practical discussions over risk assessment and new technologies. As the only avenue currently available for participation is through public submissions regarding specific applications, or normative participation, there is a gap in research that points to future risks at a practical level. By identifying these risks earlier a better level of preparedness may be achieved. Although it may not be ERMA's place to provide this service, some organisation should be set up to actively identify relevant local knowledge on the potential implications of technologies. However, ERMA's Public Awareness Group may be qualified to perform this function. Currently their role is to conduct:

Public awareness programmes, corporate communications, Website management and the overview of stakeholder relationships (New Zealand. Environmental Risk Management Authority (a)).

As the Public Awareness Group is responsible for an 'overview of stakeholder relationships', a similar function of identifying the social environments likely to interact with the new organism or substance may also be possible. From this it would be possible to identify holders of local knowledge in those particular areas of interaction. Some findings from these types of investigations will inevitably be speculative and perhaps eventually redundant (if, for example, the technology does not proceed as expected); however the results of the approach employed by this thesis has suggested it is possible to project general directions in which a technology is headed, and then to identify possible risk implications associated with those directions.

As applicants are responsible for conducting their own assessment of risk, it may be unlikely that relevant local knowledge will be considered in their equation. A more formal methodology for applicants to conduct risk assessment may need to be provided. Identification of local knowledge before pre-application stage may be useful, as well as a provision of guideline questions to be asked. This would be

similar to the proposed ethical framework, in which applicants would be required to “[i]nitiate early discussions with stakeholders who may have significant ethical concerns or questions” at a pre-application stage; in this case, early consultation with holders of relevant ‘local knowledge’ could be required (New Zealand. Environmental Risk Management Authority 2005 (a), p.9). This would enable applicants to conduct earlier assessment of social implications and risks of the technology and of proposed risk management procedures than is currently conducted.

It is also important to take on board the complexity and ambiguity that accompanies commercial applications of animal biopharming and other lab-developed technologies. The interviews suggested that risk will be contingent upon immeasurable factors, for instance attitude and human error. Thus, risk should not be presented as entirely controllable or quantifiably measurable. Risk assessment within New Zealand should allow for unknown variables: whilst this need not mean a complete ban on new technologies, a certain level of acknowledgement of the unknown and uncontrollable could allow for better planning. For example, the current liability laws are contingent upon someone violating ERMA approval conditions; any costs resulting from an unexpected (or uncontrolled for) problem will be borne by society as a whole. To avoid this, liability laws and risk assessments should reflect the understanding shown by the interview participants of the complexities and uncertainties of interactions between technologies and their social and environmental contexts. Terry et.al (2001) suggests several viable options for legislation to achieve this. For example, they suggest that strict liability should be enforced. Strict liability is defined as:

Anyone who sells or uses any genetically modified organism is subject to liability for physical harm, damage or economic loss to property caused by that organism. This principle extends to pure economic loss, including where an organic farmer loses accreditation with an industry representative body. (Terry et.al 2001, p.9)

Such an approach would require those expecting to benefit from the technology to assume its risks, and would avoid unexpected, and uncontrolled for, liability being borne by society. They also suggest that insurance should be mandatory for applicants to ERMA, as well as a bond, to cover possible liability claims (Terry et.al 2001, p.9). This once again ensures that unexpected liability claims can be paid, and do not fall to

society. These measures would build into the regulatory process a shift away from a paradigm that assumes controllability and predictability, toward an acknowledgement of the complexities and uncertainties embodied by the technologies and their social interactions.

Finally, as suggested in the conclusion of Chapter Six, a reworking of the conception of benefit analysis may be needed. While it is undoubtedly true that animal biopharming has the potential to benefit some people, it is not clear that significant benefit will accrue to New Zealand or New Zealanders. Including local knowledge within risk assessment processes will better illustrate who is to benefit, and result in more adequate assessment of the claims of those seeking to develop new technologies. In the interviews, several farmers gave practical reasons why animal biopharming may not be of benefit to the average New Zealand dairy farmer, or indeed, to the general dairy industry within New Zealand. This illustrates that benefit can be analysed at a micro level, involving the practicalities of the everyday and of ownership structures, rather than purely at the macro level of consumer demand for a product, or a normative level of ethical consideration from the public. Such an approach would better meet the requirement stated in *Assessment of Economic Risks, Costs and Benefits: Consideration of impacts on the Market economy* (2005 (b), p. 9), that ERMA must consider distribution of costs and benefits across society, and would enable an analysis of whether such costs and benefits are relevant to New Zealanders or merely overseas interests.

Limitations and areas for further research

In seeking to identify the social dimension of the risks of animal biopharming, this thesis has several limitations. This next section will briefly discuss these.

The focus of this thesis has been on the implications of production processes rather than end uses of the product. For example, it did not view the social implications of animal biopharming from a perspective of the patient who may use biopharmaceutical health products. It may be useful to study the knowledge of patients in regards to whether the use of animal biopharming would affect them in any way. It also did not explore in detail the risks to consumers of inadvertently consuming biopharmaceutical milk. Other social implications relating to end uses of the biopharmed product may

develop from a move toward medical foods or nutraceuticals; for example, milk as a nutraceutical, or functional food, is a possible product of animal biopharming. It is possible that the focus on engineering new 'health properties' into foods could have larger economic, distributional, or public health implications related to public behaviour towards eating, consuming and health care. This may be an interesting area of further research.

This study also did not focus on the multiple issues of animal welfare that arise in relation to animal biopharming, nor did it investigate the changing social dynamic between animals and humans that may develop using animals for medical purposes. This could be of particular concern when the boundaries between human and animal genetics become blurred due to modification. Although this is a potential social implication of animal biopharming, it is not considered within the scope of this thesis, and perhaps lies more within the normative arena of study. However, it may be important to investigate this change in the future.

As a result of the time and resource constraints on the research (typical of a Masters' thesis), areas for further research and investigation suggested in the interviews could not be followed up. Interview participants identified several more individuals and communities that would be useful to research in order to understand the implications of animal biopharming. Meat workers, milk transporters, share milkers and organic farmers may hold useful knowledge that may differ from or add to the knowledge offered by dairy farmers. Meat workers and milk transporters may be able to discuss the practicality of working with and separating GM products from non-GM products, and whether their everyday practices would pose risks in this regard. This could be vital knowledge if culled GM animals will be allowed to be used for food in any way. For milk transportation, useful information on transporting smaller amounts of milk, or keeping milk separate could be obtained. One interview participant suggested that organic farmers might hold valuable sources of knowledge. Organic farmers hold useful information in maintaining separation of organic produce from non-organic produce and following reasonably strict procedures. Although they themselves would not operate a biopharming system, parallels exist between the practices of organic farming and animal biopharming practices that may be conducted. Further risks,

implications or practical difficulties could be highlighted through conducting interviews with organic farmers.

Farm owners were interviewed because scoping of the literature identified that animal biopharming would benefit dairy farmers through increased returns. However, by interviewing only owners, a valuable area of knowledge has been missed. Share milkers and farm managers will hold a different perspective and knowledge on farming practices than the farm owners who were interviewed for this thesis. As animal biopharming may be operated by farm managers, this is a particularly important area for further research. For example, farm managers' knowledge may be helpful in identifying attitudes toward and practices of rule-following from a non-owner perspective. Many of the participants in this study made statements about farm-manager and share-milker behaviour, from their experiences; however, it would be useful to understand these factors from non-owner perspectives.

Dairy farming within New Zealand differs in attitude and practice between regions and provinces, as well as within them. While this thesis did interview farmers with various experiential backgrounds from Waikato, Taranaki and Canterbury, it may be worth researching how animal biopharming could influence each different region, specifically and uniquely, in more detail. This would be of particular value given the potential for conflict between local governments and ERMA identified in Chapter Six. If different risks are identifiable depending on region, it may point to a legitimate role for local governments in making decisions about risk.

Finally, factors that will affect animal biopharming in New Zealand will not always originate from within New Zealand but from international forces, including economic drivers and law. Whilst the interviews briefly discussed this point, further research into this area may be beneficial in understanding the implications of animal biopharming. For example, the implications of animal biopharming in New Zealand will in large part be dependent on attitudes, regulation and risk assessment of consumers, intermediaries (such as large retailers or audit systems) and government agencies overseas. Likewise, as it is almost a certainty that animal biopharming will be developed through foreign investment, knowledge about international investment

forces and multinational organisational behaviour may shed light on the implications of animal biopharming in New Zealand.

Conclusion

Animal biopharming is not yet in commercial production; in the event that it never reaches this stage, many of the practical findings of this thesis could be considered redundant. That is, as they seek to anticipate risk, they are necessarily speculative. Whilst this is a limitation, it is a limitation of risk assessment in general. It is better to think about risk earlier, than to be unprepared for negative effects when they arrive. In addition, the public would be better served by discussing social risks earlier, so they can make more accurate assessments when an application is presented for public comment. In the case of animal biopharming, this thesis has identified several areas which need to be addressed before it can be considered a safe or worthwhile investment for either New Zealanders in general or dairy farmers. Perhaps more importantly, the findings have supported the contention that local knowledge can contribute practically to risk assessment and decisions over new technologies.

Thus, a new approach to risk assessment must be undertaken. In order to do this, a re-conceptualisation of risk may be required. Knowledge of local environments and social practices should be pursued and valued as much as technological and policy 'expertise' that is currently considered. This does not suggest a wholesale change in current processes that analyse risk, for instance scientific investigation and normative discussion, but an overall enhancement of these techniques through combination with relevant local knowledge. It is an apparently simple premise, that those who will use a technology may hold useful information on its implications; however, it is also one that may allow for a better understanding of the complexities of risk, and better decision making in the future.

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Legislation

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APPENDIX 1

David Shamy
 School of Political Science and Communication
 University of Canterbury
 Private Bag 4800
 Christchurch

Date

CONSENT FORM

Project name: "The Social Implications of Animal Biopharming in New Zealand"

I have read and understood the description of the above-named project. On this basis I agree to participate as a subject in the project, and I consent to publication of the results of the project with the understanding that anonymity will be preserved unless I explicitly consent to waive anonymity.

I understand also that I may at any time withdraw from the project, including withdrawal of any information I have provided.

When data I have provided (through an interview) is used in the project, I wish the source of the data to be referred to in the following way (please tick ONE):

☐ completely anonymously (e.g., Participant 3)

☐ by general occupational or functional description (e.g., scientist, researcher, science manager, farmer, etc.) PLEASE SUPPLY

☐ by specific position title, where applicable; PLEASE SUPPLY

☐

☐ by name or name and position; PLEASE SUPPLY

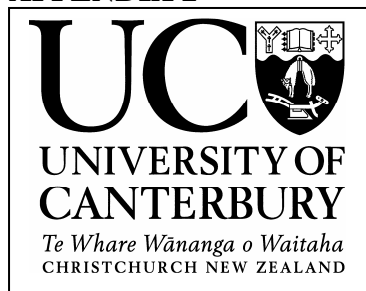
☐

NAME (please print):

Signature:

Date:

APPENDIX 2



College of Arts

School of Political Science and Communication
Political Science Programme

**“The Social Implications of Animal Biopharming”
Information Sheet**

You are invited to participate as a key informant in the research project “The Social Implications of Animal Biopharming in New Zealand”.

The aim of this project is to increase understanding of the potential social implications of animal biopharming technologies in New Zealand. This will be done by exploring, first, the likely trajectory of development of animal biopharming in New Zealand, and, second, the working environments with which animal biopharming technologies are most likely to interact. Interviews with knowledgeable people will be a major source of information in these areas.

Your participation in this project will involve an individual or group interview. It is your decision whether the interview will occur individually or in a group setting. It is expected that the interview will take between one and two hours.

You are not obliged to answer questions and you have the right to terminate the interview at any time. You also have the right to withdraw from the project at any time, including withdrawal of any information provided.

You will be asked to consent to the audio-taping of the interview. If you consent to the audio-taping of the interview, you will be offered the opportunity to check the transcript of the interview.

The results of the project may be published, but you may be assured of the complete confidentiality of data gathered in this investigation: the identity of participants will not be made public without their consent. To ensure anonymity and confidentiality, data will be held in locked filing cabinets. Data may be held on password-protected individual computer hard-drives, but will not be held on shared servers, due to the possibility of unauthorised access.

The transcripts of the interviews will be analysed and the findings will be written up for completion of a M.A thesis in Political Science and the data will be available to the biopharming subproject within the Constructive Conversations/Whakaaetanga Korero research programme.

If portions of your interview transcript are included in such presentations or publications you will not be identified in any way, unless you explicitly choose to be named.

This research is being carried out by David Shamy, in order to fulfil the requirements for the M.A. degree. The project is part of FRST contract UOCX0221 (Constructive conversations: Biotechnologies, dialogue and informed decision-making), led by Rosemary DuPlessis and Dr. Joanna Goven (University of Canterbury). Should you have any questions, please contact Joanna Goven at 03 364 2106 or joanna.goven@canterbury.ac.nz.

APPENDIX 3

Project Description

The Social Implications of Animal Biopharming in New Zealand
University of Canterbury M.A. project in conjunction with the Constructive
Conversations Programme (FRST contract UOCX0221)

David Shamy

New Zealand's government has identified biotechnology as an extremely important area in which economic growth can be maintained or increased. New Zealand's strong agricultural experience, freedom from animal disease and emphasis on developing a knowledge economy may offer an attractive environment in which to explore some aspects of biotechnology. One such opportunity that has been identified is animal biopharming.

The aim of this project is to increase understanding of the potential social implications of animal biopharming technologies in New Zealand. This will be done by exploring, first, the likely trajectory of development of animal biopharming in New Zealand, and, second, the working environments with which animal biopharming technologies are most likely to interact. Interviews with knowledgeable people will be a major source of information in these areas.

The Royal Commission report in 2002 on biotechnology recommends that research be carried out on the socio-economic and ethical effects of biotechnology within New Zealand. Such research both builds trust between the general public, policy makers and science researchers, and increases understanding for both the public and science researchers alike. This project aims to build upon this understanding by interviewing both experts in the field and local members of the public who may interact with the technology. By expanding our knowledge of how animal biopharming will affect New Zealand, particularly those likely to interact with the technology, we can be better prepared for its implementation.

APPENDIX 4**Question guide for farm interviews:**

Can you envision any risks of animal biopharming given the background material provided?

Would you be concerned if a neighbour of yours decided to start farming bioreactors? What would you be concerned about?

What would be the practical implications of upholding the cows' separation, and the separation of their milk, given how dairying practices work now?

What might have to change in dairy practices now, to make it safer?

Do you think that the different management scenarios outlined could affect the safety of biopharming?

Would different scenarios effect your decision to produce or not produce pharmaceuticals through animal biopharming?

How would you keep milk at a higher level of cleanliness?

How would you maintain a secure milk transportation system?

There will need to be counting and monitoring of the animals each day, is this achievable?

What are the practical issues for dairy milk owners to cull excess animals, without selling them?

What are the practical implications of working with smaller or larger herds of animals? What does this mean for the safety of the operation?

Do you think farmers will be able to separate animals on the one farm?

If animal biopharming affected soil, how would you contain this soil?

In your mind is animal biopharming worth pursuing given the issues we have discussed?